



# Federal Register

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2-20-03

Vol. 68 No. 34

Pages 8153-8444

Thursday

Feb. 20, 2003



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# Contents

## Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

### Agency for Toxic Substances and Disease Registry

#### NOTICES

Hazardous substances releases and facilities:

Public health assessments and effects; list, 8297

### Agricultural Marketing Service

#### NOTICES

Celery (frozen); grade standards, 8196–8197

### Agriculture Department

*See* Agricultural Marketing Service

*See* Forest Service

*See* National Agricultural Statistics Service

*See* Rural Business-Cooperative Service

#### NOTICES

Agricultural payment limitations application, 8195–8196

### Alcohol, Tobacco and Firearms Bureau

#### PROPOSED RULES

Firearms:

Commerce in explosives—

Fireworks; correction, 8331

### Army Department

*See* Engineers Corps

### Centers for Medicare & Medicaid Services

#### NOTICES

Organization, functions, and authority delegations:

Health Insurance Portability and Accountability Act

Standards Office, 8297–8299

### Central Security Service/National Security Agency

*See* National Security Agency/Central Security Service

### Coast Guard

#### NOTICES

Agency information collection activities:

Proposed collection; comment request, 8324–8325

Meetings:

Towing Safety Advisory Committee, 8325–8326

Reports and guidance documents; availability, etc.:

Merchant mariners—

Document renewals and issuances; forms and procedures, 8326

### Commerce Department

*See* International Trade Administration

*See* National Institute of Standards and Technology

*See* National Oceanic and Atmospheric Administration

#### NOTICES

Reports and guidance documents; availability, etc.:

Small entities consideration in rulemaking, 8201–8202

### Customs Service

#### NOTICES

General program test:

Post-entry amendment processing; extension, 8329–8330

### Defense Department

*See* Defense Information Systems Agency

*See* Defense Logistics Agency

*See* Engineers Corps

*See* National Security Agency/Central Security Service

#### NOTICES

Agency information collection activities:

Proposed collection; comment request, 8226

Submission for OMB review; comment request, 8226–8227

Federal Acquisition Regulation (FAR):

Agency information collection activities—

Submission for OMB review; comment request, 8227–8228

Meetings:

Capabilities for Domestic Response to Terrorist Attacks

Involving Weapons of Mass Destruction Advisory

Panel, 8229

Electron Devices Advisory Group, 8229–8230

Science Board, 8229

Privacy Act:

Systems of records, 8230–8231

### Defense Information Systems Agency

#### NOTICES

Privacy Act:

Systems of records, 8231–8232

### Defense Logistics Agency

#### NOTICES

Privacy Act:

Systems of records, 8232–8233

### Drug Enforcement Administration

#### NOTICES

*Applications, hearings, determinations, etc.:*

Chattem Chemicals, Inc., 8307

### Education Department

#### NOTICES

Agency information collection activities:

Proposed collection; comment request, 8233–8234

Submission for OMB review; comment request, 8234

Reports and guidance documents; availability, etc.:

Elementary and secondary education—

Alabama Department of Education; compliance agreement findings, 8234–8260

Idaho State Department of Education; compliance agreement findings, 8261–8285

### Energy Department

*See* Federal Energy Regulatory Commission

### Engineers Corps

#### NOTICES

Jurisdictional transfers:

Joliet Army Ammunition Plant, IL; portion to Agriculture

Department for Midewin National Tallgrass Prairie, 8233

### Federal Aviation Administration

#### PROPOSED RULES

Airworthiness directives:

McDonnell Douglas, 8155–8157

NARCO Avionics Inc., 8161–8162

Rolls-Royce plc, 8157–8161

**NOTICES**

## Meetings:

Harmonization Work Program, 8326–8327

**Federal Energy Regulatory Commission****NOTICES**

## Electric rate and corporate regulation filings:

Sithe New Boston, LLC, et al., 8291–8292

## Hydroelectric applications, 8292–8295

*Applications, hearings, determinations, etc.:*

AIM Pipeline, LLC, 8286

Algonquin Gas Transmission Co., 8286–8287

Alliance Pipeline L.P., 8287

Columbia Gas Transmission Corp., 8288

Columbia Gulf Transmission Co., 8288

Guardian Pipeline Company, L.L.C., 8288–8289

North Branch Resources, LLC, 8289

Northern Natural Gas Co., 8289

Pacific Gas and Electric Co., 8289–8290

PG&E Gas Transmission, Northwest Corp., 8290

Pine Needle LNG Co., LLC, 8290

San Diego Gas & Electric Co. et al., 8291

**Federal Highway Administration****NOTICES**

## Environmental statements; notice of intent:

Bronx County, NY, 8327–8328

**Federal Maritime Commission****NOTICES**

## Agreements filed, etc., 8296

## Ocean transportation intermediary licenses:

J.M.C. Transport Corp., et al., 8296

Reliable Van & Storage Co., Inc. et al., 8296

**Fish and Wildlife Service****NOTICES**

## Comprehensive conservation plans; availability, etc.:

Agassiz National Wildlife Refuge, MN, 8303–8304

**Food and Drug Administration****RULES**

## Animal drugs, feeds, and related products:

Oxytetracycline injection, 8153

**PROPOSED RULES**

## Food for human consumption:

Food labeling—

Nutrient content claims; sodium levels definition for term “healthy”, 8163–8179

**NOTICES**

## Agency information collection activities:

Reporting and recordkeeping requirements, 8299

## Meetings:

Food Advisory Committee, 8299–8300

Oncological Drugs Advisory Committee, 8300

**Forest Service****NOTICES**

## Meetings:

Resource Advisory Committees—

Siskiyou National Forest, 8197

## Reports and guidance documents; availability, etc.:

Cabin User Fee Fairness Act; implementation—

Recreation residences permits fees determination, 8197

**General Services Administration****NOTICES**

## Federal Acquisition Regulation (FAR):

Agency information collection activities—

Submission for OMB review; comment request, 8227–8228

## Reports and guidance documents; availability, etc.:

Annual motor vehicle acquisition reports; Web site access, 8296

**Health and Human Services Department**

*See* Agency for Toxic Substances and Disease Registry

*See* Centers for Medicare & Medicaid Services

*See* Food and Drug Administration

**RULES**

## Health insurance reform:

Health Insurance Portability and Accountability Act of 1996—

Security standards, 8333–8381

Transactions and code set standards for electronic transactions; modifications, 8380–8399

**NOTICES**

## Scientific misconduct findings; administrative actions:

Ganz, Michael, E., M.D.; correction, 8296–8297

**Housing and Urban Development Department****NOTICES**

## Agency information collection activities:

Proposed collection; comment request, 8301

Submission for OMB review; comment request, 8301–8302

Mortgage Review Board; administrative actions, 8302–8303

**Immigration and Naturalization Service****NOTICES**

## Agency information collection activities:

Submission for OMB review; comment request, 8307–8308

**Interior Department**

*See* Fish and Wildlife Service

*See* Land Management Bureau

*See* Minerals Management Service

**International Trade Administration****NOTICES**

## Antidumping:

Cut-to-length carbon steel plate from—

Mexico, 8202–8203

Polyvinyl alcohol from—

Japan, 8203–8210

*Applications, hearings, determinations, etc.:*

National Renewable Energy Laboratory, 8210

University of—

Kentucky et al., 8210

**Justice Department**

*See* Drug Enforcement Administration

*See* Immigration and Naturalization Service

*See* National Institute of Corrections

**Land Management Bureau****NOTICES**

## Environmental statements; availability, etc.:

South Powder River Basin Coal, WY; draft and hearing, 8304–8306

## Meetings:

Resource Advisory Councils—

Northwest California, 8306

**Minerals Management Service****RULES**

Outer Continental Shelf; oil, gas, and sulfur operations:  
Oil and gas drilling requirements, 8401–8435

**NOTICES**

Outer Continental Shelf operations:  
Alaska region—  
Oil and gas lease sales, 8306

**National Aeronautics and Space Administration****NOTICES**

Federal Acquisition Regulation (FAR):  
Agency information collection activities—  
Submission for OMB review; comment request, 8227–  
8228

**National Agricultural Statistics Service****NOTICES**

Meetings:  
Agriculture Statistics Advisory Committee, 8197–8198

**National Institute for Literacy****NOTICES**

Meetings:  
National Institute for Literacy Advisory Board, 8313

**National Institute of Corrections****NOTICES**

Grants and cooperative agreements; availability, etc.:  
Executive Training for Women-Team Development, 8308–  
8311  
Operational Practices for Women Offenders, 8311–8313

**National Institute of Standards and Technology****NOTICES**

Grants and cooperative agreements; availability, etc.:  
Small grants programs, 8211–8226

**National Oceanic and Atmospheric Administration****RULES**

Fishery conservation and management:  
Alaska; fisheries of Exclusive Economic Zone—  
Pacific cod, 8154  
Red king crab, 8153–8154

**National Security Agency/Central Security Service****PROPOSED RULES**

Privacy Act; implementation, 8179–8194

**Public Health Service**

See Agency for Toxic Substances and Disease Registry  
See Food and Drug Administration

**Rural Business-Cooperative Service****NOTICES**

Grants and cooperative agreements; availability, etc.:  
State Rural Development Council; recognition  
applications, 8198–8201

**Securities and Exchange Commission****RULES**

Investment companies:  
Investment company assets with a securities depository;  
custody, 8437–8443

**NOTICES**

Agency information collection activities:  
Submission for OMB review; comment request, 8313–  
8314  
Consolidated Tape Association and Quotation Plans;  
amendments, 8314–8316  
Self-regulatory organizations; proposed rule changes:  
American Stock Exchange LLC, 8316  
Chicago Board Options Exchange, Inc., 8316–8318  
New York Stock Exchange, Inc., 8318–8319  
Pacific Exchange, Inc., 8319–8322  
Philadelphia Stock Exchange, Inc., 8322–8324

**State Department****NOTICES**

Meetings:  
International Economic Policy Advisory Committee, 8324

**Statistical Reporting Service**

See National Agricultural Statistics Service

**Toxic Substances and Disease Registry Agency**

See Agency for Toxic Substances and Disease Registry

**Transportation Department**

See Coast Guard  
See Federal Aviation Administration  
See Federal Highway Administration

**Treasury Department**

See Alcohol, Tobacco and Firearms Bureau  
See Customs Service

**NOTICES**

Agency information collection activities:  
Submission for OMB review; comment request, 8328–  
8329

---

**Separate Parts In This Issue****Part II**

Health and Human Services Department, 8333–8399

**Part III**

Interior Department, Minerals Management Service, 8401–  
8435

**Part IV**

Securities and Exchange Commission, 8437–8443

---

**Reader Aids**

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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**CFR PARTS AFFECTED IN THIS ISSUE**

---

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

**14 CFR****Proposed Rules:**

39 (3 documents) ...8155, 8157,  
8161

**17 CFR**

270.....8438

**21 CFR**

522.....8153

**Proposed Rules:**

101.....8163

**27 CFR****Proposed Rules:**

55.....8331

**30 CFR**

250.....8402

**32 CFR****Proposed Rules:**

322.....8179

**45 CFR**

160.....8334

162 (2 documents) .....8334,  
8381

164.....8334

**50 CFR**

679 (2 documents) .....8153,  
8154

# Rules and Regulations

Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

**DATES:** This rule is effective February 20, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Terr., St. Joseph, MO 64506-0457, filed a supplement to approved ANADA 200-123 that provides for the use of MAXIM-200 (oxytetracycline) Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of this oxytetracycline injectable solution to lactating dairy cattle. The supplemental ANADA is approved as of November 19, 2002, and the regulations are amended in 21 CFR 522.1660 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### § 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) in the eighth sentence by removing "sponsors 059130 and 061623"; and adding in its place "sponsor 061623"; and in the ninth sentence by removing "and 055529" and adding in its place "055529, and 059130".

Dated: January 21, 2003.

**Steven F. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. 03-3434 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 021212307-2307-01; I.D. 021303C]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish by Vessels Using Non-Pelagic Trawl Gear in the Red King Crab Savings Subarea

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for groundfish with non-pelagic trawl gear in the red king crab savings subarea (RKCSS) of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the interim 2003 red king crab prohibited species catch (PSC) limit that is specified for the RKCSS of the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), February 14, 2003, until superseded by the notice of Final 2003 Harvest Specifications of Groundfish for the BSAI, which will be published in the **Federal Register**.

#### FOR FURTHER INFORMATION CONTACT:

Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and CFR part 679.

The interim 2003 red king crab PSC limit that is specified for the RKCSS of the BSAI is 5,231 animals as established by the interim 2003 harvest specifications for Groundfish of the BSAI (67 FR 78739, December 26, 2002).

In accordance with § 679.21(e)(7)(ii)(B), the Administrator, Alaska Region, NMFS, has determined that the amount of the interim 2003 red

king crab PSC limit specified for the RKCSS will be caught. Consequently, NMFS is closing the RKCSS to directed fishing for groundfish with non-pelagic trawl gear.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the interim 2003 red king crab PSC limit, and therefore reduce the public's ability to use and enjoy the fishery resource.

The Assistant Administrator for Fisheries, NOAA, also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.21 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

**Dated:** February 14, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03-4103 Filed 2-14-03; 2:17 pm]

**BILLING CODE 3510-12-S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 021212306-2306-01; I.D. 021403C]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Catching Pacific Cod for Processing by the Inshore Component in the Western Regulatory Area of the Gulf of Alaska

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the interim 2003 total allowable catch (TAC) of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), February 17, 2003, until superseded by the notice of Final 2003 Harvest Specifications of Groundfish for the GOA, which will be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The interim 2003 TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the GOA is 7,979 metric tons (mt) as established by the interim 2003 harvest specifications of groundfish for the GOA (67 FR 78733, December 26, 2002).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the interim 2003 TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 7,929 mt, and is setting aside the remaining 50 mt as bycatch to support other anticipated groundfish fisheries. In accordance with

§ 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the GOA.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the interim TAC, and therefore reduce the public's ability to use and enjoy the fishery resource.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

**Dated:** February 14, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03-4104 Filed 2-14-03; 2:17 pm]

**BILLING CODE 3510-22-S**



# Proposed Rules

Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2001-NM-77-AD]

#### Airworthiness Directives; Various Transport Category Airplanes Manufactured by McDonnell Douglas

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the adoption of a new airworthiness directive (AD) that is applicable to various transport category airplanes manufactured by McDonnell Douglas. This proposal would require a one-time test of the fire extinguishers for the engine and auxiliary power unit (APU) to determine the capability of the fire electrical circuits to fire discharge cartridges, and troubleshooting actions, if necessary. This action is necessary to prevent failure of the fire extinguishers to fire discharge cartridges, which could result in the inability to put out a fire in an engine or in the APU. This action is intended to address the identified unsafe condition.

**DATES:** Comments must be received by April 7, 2003.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2001-NM-77-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: [9-anm-nprmcomment@faa.gov](mailto:9-anm-nprmcomment@faa.gov). Comments sent via fax or the Internet must contain "Docket No. 2001-NM-77-AD" in the subject line and need not be submitted

in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1-L5A (D800-0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

**FOR FURTHER INFORMATION CONTACT:** Samuel Lee, Aerospace Engineer, Propulsion Branch, ANM-140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712-4137; telephone (562) 627-5262; fax (562) 627-5210.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by

interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2001-NM-77-AD." The postcard will be date stamped and returned to the commenter.

#### Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2001-NM-77-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

#### Discussion

The FAA has received reports indicating that fire extinguishers for the engine and the auxiliary power unit (APU) had failed to discharge when commanded on a McDonnell Douglas Model DC-9-81 airplane and a Model DC-9-33F airplane. In one event, investigation revealed contamination of the circuit breaker contacts. In the other, investigation revealed high resistance of the discharge switch electrical contacts.

This condition, if not corrected, could result in failure of the fire electrical circuits to fire the discharge cartridges, which could result in the inability to put out a fire in an engine or APU.

#### Similar Models

The fire extinguisher system on the following airplane models are equipped with fire system fire extinguishers: Model DC-8-11, DC-8-12, DC-8-21, DC-8-31, DC-8-32, DC-8-33, DC-8-41, DC-8-42, and DC-8-43 airplanes; Model DC-8-50 series airplanes; Model DC-8F-54 and DC-8F-55 airplanes; Model DC-8-60 series airplanes; Model DC-8-61F, DC-8-62F, and DC-8-63F airplanes; Model DC-8-70 series airplanes; Model DC-8-71F, DC-8-72F, and Model DC-8-73F airplanes; Model DC-9-10 series airplanes; Model DC-9-20 series airplanes; Model DC-9-30 series airplanes; Model DC-9-40 series airplanes; Model DC-9-50 series airplanes; Model DC-10-10 and DC-10-10F airplanes; Model DC-10-15 airplanes; Model DC-10-30, DC-10-30F (KC10A and KDC-10) airplanes; Model

DC-10-40 and DC-10-40F airplanes; Model MD-10-10F and MD-10-30F airplanes; Model MD-11 and -11F airplanes; Model MD-88 airplanes; and Model MD-90-30 airplanes. Therefore,

all of these models may be subject to the same unsafe condition.

#### Explanation of Relevant Service Information

The FAA has reviewed and approved the Boeing and McDonnell Douglas

Alert Service Bulletins (ASBs) as applicable to the appropriate airplane models specified in the following table.

McDonnell Douglas Models—	As listed in—
Model DC-8-11, DC-8-12, DC-8-21, DC-8-31, DC-8-32, DC-8-33, DC-8-41, DC-8-42, and DC-8-43 airplanes; DC-8-51, DC-8-52, DC-8-53, and DC-8-55 airplanes; DC-8F-54 and DC-8F-55 airplanes; DC-8-61, DC-8-62, and DC-8-63 airplanes; DC-8-61F, DC-8-62F, and DC-8-63F airplanes; DC-8-71, DC-8-72 and DC-8-73 airplanes; DC-8-71F, DC-8-72F, and DC-8-73F airplanes.	Boeing Alert Service Bulletin DC 8-26A042, including Appendix A and Evaluation Form, dated January 31, 2002.
Model DC-9-11, DC-9-12, DC-9-13, DC-9-14, DC-9-15, and DC-9-15F airplanes; DC-9-21 airplanes; DC-9-31, DC-9-32, DC-9-32 (VC-9C), DC-9-32F, DC-9-33F, DC-9-34, DC-9-34F, and DC-9-32F (C-9A, C-9B) airplanes; DC-9-41 airplanes; DC-9-51 airplanes; DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), and DC-9-87 (MD-87) airplanes; and MD-88 airplanes.	McDonnell Douglas Alert Service Bulletin DC9-26A029, Revision 01, including Evaluation Form, dated May 8, 2001.
Model DC-10-10 and DC-10-10F airplanes; DC-10-15 airplanes; DC-10-30 and DC-10-30F (KC10A and KDC-10) airplanes; DC-10-40 and DC-10-40F airplanes; MD-10-10F and MD-10-30F airplanes.	McDonnell Douglas Alert Service DC10-26A050, including Evaluation Form, dated July 31, 2000.
Model MD-11 and MD-11F airplanes .....	McDonnell Douglas Alert Service Bulletin MD11-26A039, Revision 01, including Evaluation Form, dated November 21, 2002.
Model MD-90-30 airplanes .....	McDonnell Douglas Alert Service Bulletin MD90-26A005, including Evaluation Form, dated July 31, 2000.

These ASBs describe procedures for a one-time test of the fire extinguishers for the engines and APU to determine the capability of the fire electrical circuits to fire discharge cartridges.

Additionally, the ASBs reference the airplane maintenance manual (AMM) for additional information on troubleshooting procedures in the event any test fails. Accomplishment of the actions specified in the applicable ASB is intended to adequately address the identified unsafe condition.

#### Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the ASBs described previously, except that this proposed AD would not require completion of any Evaluation Forms that are attached to the ASBs described previously.

#### Cost Impact

There are approximately 3,311 airplanes of the affected designs in the worldwide fleet. The FAA estimates that 1,553 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately between 4 work hours and 7 work hours per airplane (depending upon airplane model) to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Based on these

figures, the cost impact of the proposed AD on U.S. operators is estimated to be between \$372,720 and \$652,260, or between \$240 and \$420 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

#### Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if

promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**McDonnell Douglas:** Docket 2001-NM-77-AD.

*Applicability:* This AD applies to the airplanes listed in the following Table of this AD, certificated in any category:

TABLE.—APPLICABILITY

McDonnell Douglas Models—	As listed in—
Model DC-8-11, DC-8-12, DC-8-21, DC-8-31, DC-8-32, DC-8-33, DC-8-41, DC-8-42, and DC-8-43 airplanes; DC-8-51, DC-8-52, DC-8-53, and DC-8-55 airplanes; DC-8F-54 and DC-8F-55 airplanes; DC-8-61, DC-8-62, and DC-8-63 airplanes; DC-8-61F, DC-8-62F, and DC-8-63F airplanes; DC-8-71, DC-8-72 and DC-8-73 airplanes; DC-8-71F, DC-8-72F, and DC-8-73F airplanes.	Boeing Alert Service Bulletin DC 8-26A042, including Appendix A and Evaluation Form, dated January 31, 2002
Model DC-9-11, DC-9-12, DC-9-13, DC-9-14, DC-9-15, and DC-9-15F airplanes; DC-9-21 airplanes; DC-9-31, DC-9-32, DC-9-32 (VC-9C), DC-9-32F, DC-9-33F, DC-9-34, DC-9-34F, and DC-9-32F (C-9A, C-9B) airplanes; DC-9-41 airplanes; DC-9-51 airplanes; DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), and DC-9-87 (MD-87) airplanes; and MD-88 airplanes.	McDonnell Douglas Alert Service Bulletin DC9-26A029, Revision 01, including Evaluation Form, dated May 8, 2001.
Model DC-10-10 and DC-10-10F airplanes; DC-10-15 airplanes; DC-10-30 and DC-10-30F (KC10A and KDC-10) airplanes; DC-10-40 and DC-10-40F airplanes; MD-10-10F and MD-10-30F airplanes.	McDonnell Douglas Alert Service DC10-26A050, including Evaluation Form, dated July 31, 2000.
Model MD-11 and MD-11F airplanes .....	McDonnell Douglas Alert Service Bulletin MD11-26A039, Revision 01, including Evaluation Form, dated November 21, 2002
	McDonnell Douglas Alert Service Bulletin MD90-26A005, including Evaluation Form, dated July 31, 2000.
Model MD-90-30 airplanes .....	

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent failure of the engine and auxiliary power unit (APU) fire extinguishers to fire discharge cartridges, which could result in the inability to put out a fire in an engine or in the APU; accomplish the following:

#### Testing the Firex Electrical Circuits

(a) Within 18 months after the accumulation of 15,000 total flight hours, or within 18 months after the effective date of this AD, whichever occurs later: Test the capability of the electrical circuits of the firex fire extinguishers for the engine and the APU, per the applicable alert service bulletin (ASB) listed in the Applicability Table of this AD. However, this AD does not require completion and submission of any Evaluation Forms attached to those ASBs.

(1) If any electrical circuit of the firex fire extinguishers for the APU does not pass the testing, before further flight, accomplish the troubleshooting procedures specified in the applicable

ASB. Dispatch with an inoperative APU is permitted for the amount of time specified in the Minimum Equipment List. Dispatch after that time is not permitted until the circuits are repaired per the Boeing Standard Wiring Practices Manual (SWPM) D6-82481.

(2) If any electrical circuit of the firex fire extinguishers for the engine does not pass the testing, before further flight, accomplish the troubleshooting procedures specified in the applicable ASB and repair per SWPM D6-82481. Dispatch is not permitted until the circuits have been repaired.

#### Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

#### Special Flight Permits

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on February 12, 2003.

**Ali Bahrami,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 03-4028 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2000-NE-13-AD]

RIN 2120-AA64

#### Airworthiness Directives; Rolls-Royce RB211 Series Turbofan Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

**SUMMARY:** This notice revises an earlier proposed airworthiness directive (AD), applicable to Rolls-Royce (RR) plc RB211-535E4-37, RB211-535E4-B-37, and RB211-535E4-B-75 series turbofan engines. That proposal would have required initial and repetitive ultrasonic inspections of low pressure compressor (LPC) fan blade roots for cracks, and relubrication of LPC fan blades before reinstallation. That proposal was prompted by the discovery of cracks on LPC fan blade roots during an engine overhaul. This action revises the proposed rule by introducing an alternative technique to ultrasonically inspect installed fan blades on-wing using a surface wave ultrasonic probe. This action also adds the application of

Metco 58 blade root coating as an optional terminating action. The actions specified by this proposed AD are intended to detect cracks in LPC fan blade roots, which if not detected, could lead to uncontained multiple fan blade failure, and damage to the airplane.

**DATES:** Comments must be received by April 21, 2003.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-NE-13-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may be inspected at this location, by appointment, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: "*9-ane-adcomment@faa.gov*". Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from Rolls-Royce plc, PO Box 31, Derby, England, DE248BJ; telephone: 011-44-1332-242-424; fax: 011-44-1332-249-936. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

**FOR FURTHER INFORMATION CONTACT:** James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone: (781) 238-7176; fax: (781) 238-7199.

#### **SUPPLEMENTARY INFORMATION:**

##### **Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report

summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NE-13-AD." The postcard will be date stamped and returned to the commenter.

##### **Availability of NPRM's**

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-NE-13-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

##### **Discussion**

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to RR plc RB211-535E4-37, RB211-535E4-B-37, and RB211-535E4-B-75 series turbofan engines, was published as an NPRM in the **Federal Register** on August 9, 2001 (66 FR 41808). That NPRM would have required initial and repetitive ultrasonic inspections of LPC fan blade roots for cracks, and relubrication of LPC fan blades before reinstallation. That NPRM was prompted by the discovery of cracks on LPC fan blade roots during an engine overhaul. That condition, if not corrected, could result in uncontained multiple fan blade failure, and damage to the airplane.

The FAA received the following comments on the initial NPRM. The latest revision to RR Mandatory Service Bulletin (MSB) RB.211-72-C879, Revision 3, dated October 9, 2002, addresses those comments.

Two commenters request the incorporation of Metco 58 blade root coating as a terminating action to the AD inspection requirements.

The FAA agrees. The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), has notified the FAA that incorporation of Metco 58 blade root coating using RR Service Bulletin (SB) RB.211-72-C946, dated August 6, 2002, is considered a terminating action to the inspections. The FAA has examined the information provided by RR and the CAA and agrees with the conclusions. Incorporation of Metco 58 blade root coating has been added to the proposed AD as a terminating action.

One commenter requests a draw down inspection schedule for engines that

have not previously had repetitive inspections. The commenter states that due to the age of its fleet, it would be difficult to do repetitive inspections in accordance with the AD.

The FAA does not agree with the request due to the potential safety hazard associated with a possible multiple fan blade release. However, RR MSB RB211-72-C879, Revision 3, dated October 9, 2002, allows an alternative on-wing ultrasonic inspection method.

Since the above comments expand the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

##### **Manufacturer's Service Information**

RR has issued MSB RB.211-72-C879, Revision 3, dated October 9, 2002, that specifies ultrasonic inspection of high cyclic life blades on-wing with either the LPC fan blades in place or removed from the LPC. The CAA classified this service bulletin as mandatory and issued AD 002-01-2000 in order to ensure the airworthiness of these RR engines in the UK.

##### **Bilateral Agreement Information**

These engines are manufactured in the United Kingdom (UK), and are type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

##### **FAA's Determination of an Unsafe Condition and Proposed Actions**

Since an unsafe condition has been identified that is likely to exist or develop on other RR RB211-535E4 series turbofan engines of the same type design, that are used on Boeing 757 airplanes registered in the United States, the proposed AD would require initial and repetitive ultrasonic inspections of LPC fan blade roots on-wing and during overhaul, and relubrication, according to accumulated life cycles.

##### **Economic Analysis**

There are approximately 1,021 engines of the affected design in the worldwide fleet. The FAA estimates that 545 engines installed on aircraft of U.S.

registry would be affected by this proposed AD. It will take approximately 7.0 work hours per engine to conduct an on-wing initial inspection, and 2 hours per engine to do an overhaul initial inspection of the proposed actions. The average labor rate is \$60 per work hour. Since the actions are inspections, there are no required parts costs. Based on these figures, the FAA estimates the total cost for on-wing initial inspections only, of the proposed AD on U.S. operators, to be \$228,900, and for overhaul initial inspections only, to be \$65,400.

### Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted

with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption

### ADDRESSES.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation

Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive: Rolls-Royce plc: Docket No. 2000-NE-13-AD.

### Applicability

This airworthiness directive (AD) is applicable to Rolls-Royce (RR) plc RB211-535E4-37, RB211-535E4-B-37, and RB211-535E4-B-75 series turbofan engines with low pressure compressor (LPC) fan blades with the part numbers (P/N's) listed in the following Table 1 of this AD. These engines are installed on, but not limited to Boeing 757 and Tupolev Tu204 series airplanes. Table 1 follows:

TABLE 1.—APPLICABLE LPC FAN BLADE P/N'S

UL16135	UL16171	UL16182	UL19643	UL20044
UL20132	UL20616	UL21345	UL22286	UL23122
UL24525	UL24528	UL24530	UL24532	UL24534
UL27992	UL28601	UL28602	UL29511	UL29556
UL30817	UL30819	UL30933	UL30935	UL33707
UL33709	UL36992	UL37090	UL37272	UL37274
UL37276	UL37278	UL38029	UL38032	

**Note 1:** This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (g) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by

this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

### Compliance

Compliance with this AD is required as indicated, unless already done.

To detect cracks in LPC fan blade roots, which if not detected, could lead to uncontained multiple fan blade failure, and damage to the airplane, do the following:

(a) If you have a full set of fan blades, modified using RR SB RB.211-72-C946, dated August 6, 2002, that can be identified by a blue triangle etched on the blade airfoil suction surface close to the leading edge tip of each blade, no further action is required.

(b) On RB211-535E4 engines, operated to Flight Profile A, ultrasonically inspect, and if required, relubricate using the following Table 2:

TABLE 2.—RB211-535E4 FLIGHT PROFILE A

Engine location	Initial inspection within (CSN)	Type action	In accordance with	Repeat inspection within (CSN)
(1) On-wing .....	17,350.	(i) Root Probe, inspect and relubricate, OR. (ii) Wave Probe .....	RB.211-72-C879 Revision 3, 3.A.(1) through 3.A.(7), dated October 9, 2002. RB.211-72-C879 Revision 3, 3.B.(1) through 3.B.(7), dated October 9, 2002.	1,400. 1,150.
(2) In Shop .....	17,350.	Root Probe, inspect and relubricate.	RB.211-72-C879 Revision 3, 3.C.(1) through 3.C.(4), dated October 9, 2002.	1,400.

(c) On RB211–535E4 engines, operated to Flight Profile B, ultrasonically inspect, and if required, relubricate using the following Table 3:

TABLE 3.—RB211–535E4 FLIGHT PROFILE B

Engine location	Initial inspection within (CSN)	Type action	In accordance with	Repeat inspection within (CSN)
(1) On-wing .....	12,350.	(i) Root Probe, inspect and relubricate, OR. (ii) Wave Probe .....	RB.211–72–C879 Revision 3, 3.A.(1) through 3.A.(7), dated October 9, 2002. RB.211–72–C879 Revision 3, 3.B.(1) through 3.B.(7), dated October 9, 2002.	850. 700.
(2) In Shop .....	12,350.	Root Probe, inspect and relubricate.	RB.211–72–C879 Revision 3, 3.C.(1) through 3.C.(4), dated October 9, 2002.	850.

(d) On RB211–535E4 engines, operated to combined Flight Profile A and B, ultrasonically inspect, and if required, relubricate using the following Table 4:

TABLE 4.—RB211–535E4 FLIGHT PROFILE A AND B

Engine location	Initial inspection within (CSN)	Type action	In accordance with	Repeat inspection within (CSN)
(1) On-wing .....	65% hard life (To calculate, Compliance Section 1.C.(4)).	(i) Root Probe, inspect and relubricate, OR.  (ii) Wave Probe. ....	RB.211–72–C879 Revision 3, 3.A.(1) through see 3.A.(7), dated October 9, 2002. RB.211–72–C879 Revision 3, 3.B.(1) through 3.B.(7), dated October 9, 2002.	As current flight profile.  As current flight profile.
(2) In Shop .....	65% hard life (To calculate, Compliance Section 1.C.(4)).	Root Probe, inspect and relubricate.	RB.211–72–C879 Revision 3, 3.C.(1) through see 3.C.(4), dated October 9, 2002.	As current flight profile.

**Note 2:** Fan blades that have been operated within RB211–535E4 Flight Profile A and B will have final life as defined in the Time

Limits Manual. See References Section 1.G.(3), of MSB RB.211–72–C879, Revision 3, dated October 9, 2002.

(e) On RB211–535E4–B engines, ultrasonically inspect, and if required, relubricate using the following Table 5:

TABLE 5.—RB211–535E4–B

Engine location	Initial inspection within (CSN)	Type action	In accordance with	Repeat within (CSN) inspection
(1) On-wing. ....	17,000 .....	(i) Root Probe, inspect and relubricate OR. (ii) Wave Probe. ....	RB.211–72–C879 Revision 3, 3.A.(1) through 3.A.(7), dated October 9, 2002. RB.211–72–C879 Revision 3, 3.B.(1) through 3.B.(7), dated October 9, 2002.	1,200. 1,000.
(2) In Shop .....	17,000 .....	Root Probe, inspect and relubricate.	RB.211–72–C879 inspect and Revision 3, 3.C.(1) through 3.C.(4), dated October 9, 2002.	1,200

### Optional Terminating Action

(f) Application of Metco 58 blade root coating using RR SB RB.211–72–C946, Revision 1, dated August 6, 2002, constitutes terminating action to the repetitive inspection requirements specified in paragraphs (b), (c), (d), and (e) of this AD.

### Alternative Methods of Compliance

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

### Special Flight Permits

(h) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location

where the requirements of this AD can be done.

**Note 4:** The subject of this AD is addressed in CAA airworthiness directive AD 002-01-2000, dated October 9, 2002.

Issued in Burlington, Massachusetts, on February 10, 2003.

**Peter A. White,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 03-4057 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-13-U**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2002-NE-32-AD]

RIN 2120-AA64

#### Airworthiness Directives; NARCO Avionics Inc. AT150 Transponders

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The Federal Aviation Administration (FAA) proposes to adopt a new airworthiness directive (AD) that is applicable to certain serial numbers (SN's) of NARCO Avionics Inc. AT150 transponders. This proposal would require modification to the transponder by adding a resistor and transistor to the circuit board. This proposal is prompted by reports of AT150 transponders not recognizing and responding properly to Mode S interrogations from Mode S ground stations and Traffic Alert and Collision Avoidance System (TCAS-II) airborne equipment. The actions specified by the proposed AD are intended to prevent loss of aircraft airspace separation and the possibility of mid-air collision.

**DATES:** Comments must be received by April 21, 2003.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002-NE-32-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may be inspected at this location, by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: "[g-ane-adcomment@faa.gov](mailto:g-ane-adcomment@faa.gov)". Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from NARCO Avionics Inc., 270 Commerce Drive, Fort Washington, PA 19034; telephone (215) 643-2905; fax (215) 643-2007. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

#### FOR FURTHER INFORMATION CONTACT:

Balam Rambrich, Aerospace Engineer, New York Aircraft Certification Office, FAA, Engine and Propeller Directorate, 10 Fifth Street, 3rd floor, Valley Stream, NY 11581-1200; telephone (516) 256-7507; fax (516) 256-2716.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2002-NE-32-AD." The postcard will be date stamped and returned to the commenter.

##### Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002-NE-32-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

##### Discussion

On March 20, 2002, the FAA was made aware of twelve AT150

transponders that failed to recognize and respond to Mode S interrogations from Mode S ground stations and TCAS-II airborne equipment during random testing performed by FAA Flight Standards safety inspectors. Subsequently, the manufacturer determined that "Chassis Level A" AT150 transponders have a design error, which causes the P4 pulse not to be presented, causing the transponders to shut down. This condition, if not corrected, could result in loss of aircraft airspace separation, and the possibility of mid-air collision. This proposal is only applicable to NARCO Avionics Inc. AT150 transponders with "Chassis Level A", serial numbers 10000 through 12598 inclusive.

##### Manufacturer's Service Information

The FAA has reviewed and approved the technical contents of NARCO Avionics Inc. service bulletin (SB) AT150 No. 6, dated January 31, 2003, that describes procedures for modification of the affected transponders, by adding a resistor and transistor to the circuit board to allow proper operation and changing them to "Chassis Level B". The SB also describes procedures for transponder testing after the modification is complete.

##### FAA's Determination of an Unsafe Condition and Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other NARCO Avionics Inc. AT150 transponders of the same type design, the proposed AD would require:

- For transponders not modified in accordance with NARCO Avionics Inc. service bulletin (SB) AT150 No. 1, dated July 29, 1977, modification of "Chassis Level A" transponders, serial numbers 10000 through 12598 inclusive, by adding a resistor and transistor to the circuit board, changing transponder to "Chassis Level B", and transponder testing after the modification; AND
- For transponders modified in accordance with NARCO Avionics Inc. SB AT150 No. 1, dated July 29, 1977, changing transponder to "Chassis Level B", and transponder testing.

The actions would be required to be done in accordance with the service bulletin described previously.

##### Economic Analysis

The FAA estimates that 2,598 NARCO Avionics Inc. "Chassis Level A" AT150 transponders could be affected by this proposal if all were installed in aircraft of U.S. registry. Approximately one work hour per transponder will be needed to perform the proposed actions,

at an average labor rate of \$60 per work hour. Required parts would cost approximately \$12 per transponder. Based on these figures, the total estimated cost of the proposed AD to U.S. operators could be \$187,056.

### Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**NARCO AVIONICS INC. AT150 TRANSPONDERS:**  
Docket No. 2002–NE–32–AD.

**Applicability:** This airworthiness directive (AD) is applicable to NARCO Avionics Inc. AT150 transponders with "Chassis Level A", serial numbers (SN's) 10000 through 12598 inclusive. These transponders might be installed on, but not limited to the following aircraft:

#### Cessna Aircraft Company

172, 182, R182, T182, 206, P206, U206, TP206, 210, T210, P210, 310, E310, T310, and 421 series airplanes.

#### Twin Commander Aircraft Company

500, 520, 560, 680, 681, 685, 690, 695, and 720 series airplanes.

#### The New Piper Aircraft Corporation

PA–31, PA–32, and PA–34 series airplanes.

#### Raytheon Aircraft Company

E33, F33, G33, 35, J35, K35, L35, M35, P35, S35, V35, 36, A26, B36, D55, E55, 56, A56, 58, 58A, 95, B95, D95, and E95 series airplanes.

#### Mooney Aircraft Corporation

M20 series airplanes.

#### McDonnell Douglas Helicopter Company

Model 500N rotorcraft.

**Note 1:** This AD applies to each transponder identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For transponders that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

### Compliance

Compliance with this AD is required as indicated, unless already done.

To prevent loss of aircraft airspace separation, and the possibility of mid-air collision, do the following:

#### Transponders Not Modified In Accordance With Service Bulletin AT150 No. 1

(a) For AT150 transponders with a SN listed in this AD that are not modified in accordance with service bulletin (SB) AT150 No. 1, dated July 29, 1977, within six months after the effective date of this AD, do the following:

(1) Install resistor part number (P/N) 755610028 and transistor P/N 312180102; and

(2) Change transponder to "Chassis Level B"; and

(3) Test transponders in accordance with the Corrective Action, Testing the Modification, and Return to Service paragraphs of SB AT150 No. 6, dated January 31, 2003.

#### Transponders Modified In Accordance With Service Bulletin AT150 No. 1

(b) For AT150 transponders with a SN listed in this AD, that are modified in accordance with SB AT150 No. 1, dated July 29, 1977, do the following:

(1) Within six months after the effective date of this AD, change transponder to "Chassis Level B"; and

(2) Test transponders in accordance with the Testing the Modification paragraph of SB AT150 No. 6, dated January 31, 2003; and

(3) Perform a bench test to the transponder before returning it to service. Information on bench testing can be found in AT150 Manual P/N 03606–0600.

### Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office. Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York Aircraft Certification Office.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the New York Aircraft Certification Office.

### Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on February 12, 2003.

**Francis A. Favara,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 03–4056 Filed 2–19–03; 8:45 am]

**BILLING CODE 4910–13–U**



# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 101

[Docket Nos. 91N-384H and 96P-0500]

RIN 0910-AC49

### Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy"

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulation for sodium levels for foods that use the nutrient content claim "healthy." The agency is proposing that a previously established, but not yet implemented, more restrictive, second-tier sodium level would be permitted to take effect as a criterion that individual foods must meet to qualify to bear the term "healthy." The agency is proposing to retain the current first-tier sodium level for meal and main dish products because implementing the second-tier sodium level could result in the substantial elimination of meal and main dish products bearing the claim "healthy" from the marketplace. After evaluating data from various sources, the agency believes that the proposed sodium levels will help consumers achieve a total diet that is consistent with current dietary recommendations, as the proposed levels will give consumers a reasonable number of "healthy" products from which to choose. The agency has also revised the regulatory text for the definition of "healthy" to clarify the scope of the regulation and conform to the Presidential Memorandum instructing Federal agencies to use plain language.

**DATES:** Submit written or electronic comments by May 6, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1798.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule amending § 101.65 (21 CFR 101.65) to define the term "healthy" as an implied nutrient content claim under section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)). The final rule defined criteria for use of the implied nutrient content claim "healthy," or a related term (e.g., "health," "healthful") on individual foods, including raw, single-ingredient seafood, and game meat, and on meal and main dish products. It also established two separate timeframes in which different criteria for sodium content would be effective for foods bearing a "healthy" claim (i.e., before January 1, 1998, and after January 1, 1998).

Before January 1, 1998, under § 101.65(d)(2)(ii)(A) and (d)(2)(ii)(B), for an individual food to qualify to bear the term "healthy" or a related term, the food could contain no more than 480 milligrams (mg) of sodium (first-tier sodium level): (1) Per reference amount customarily consumed per eating occasion (reference amount); (2) per serving size listed on the product label (serving size); and (3) per 50 grams (g) for products with small reference amounts (i.e., less than or equal to 30 g or less than or equal to 2 tablespoons). After January 1, 1998 (§ 101.65(d)(2)(ii)(C)), an individual food bearing the term "healthy," or a related term, could contain no more than 360 mg of sodium (second-tier sodium level) per reference amount, per serving size, and per 50 g for products with small reference amounts. The agency derived this 360 mg sodium level by applying a 25 percent reduction to the original sodium disclosure level of 480 mg for individual foods (59 FR 24232 at 24240).<sup>1</sup>

To qualify to bear "healthy" or a related term, meal and main dish products could contain no more than 600 mg of sodium (first-tier sodium level) per serving size before January 1, 1998 (§ 101.65(d)(4)(ii)(A)), and no more

than 480 mg of sodium (second-tier sodium level) per serving size after January 1, 1998 (§ 101.65(d)(4)(ii)(B)). The agency selected the 480 mg level because it was low enough to assist consumers in meeting dietary goals, while simultaneously giving consumers who eat such foods the flexibility to consume other foods whose sodium content is not restricted; because there were many individual foods and meal-type products on the market that contained less than 600 mg sodium; and because comments suggesting other levels did not provide supporting data (59 FR 24232 at 24240). Higher levels of sodium were rejected in the earlier rulemaking (59 FR 24232 at 24239) because the agency determined higher levels would not be useful to consumers wanting to use foods labeled "healthy" to limit their sodium intake to achieve current dietary recommendations.

On December 13, 1996, FDA received a petition from ConAgra, Inc. (the petitioner) requesting that the agency amend § 101.65(d) to "eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second-tier levels of 360 mg sodium for individual foods and 480 mg sodium for meals and main dishes" (FDA Docket No. 96P-0500/CP1, p. 3). As an alternative, the petitioner requested that the January 1, 1998, effective date for the second-tier sodium levels be delayed until such time as food technology "catches up" with FDA's goal of reducing the sodium content of foods and there is a better understanding of the relationship between sodium and hypertension.

FDA responded to ConAgra's petition in the **Federal Register** of April 1, 1997 (62 FR 15390), by announcing a partial stay of the second-tier sodium levels in § 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B) until January 1, 2000. This stay was intended to allow time for FDA to: (1) Reevaluate the second-tier sodium levels based on the data contained in the petition and any additional data that the agency might receive; (2) conduct any necessary rulemaking; and (3) give industry an opportunity to respond to the rule or to any change in the rule that might result from the agency's reevaluation.

On December 30, 1997 (62 FR 67771), FDA published an advance notice of proposed rulemaking (ANPRM) announcing that it was considering whether to initiate rulemaking to reevaluate and possibly amend the implied nutrient content regulations pertaining to use of the term "healthy." FDA requested comments on whether it should propose to amend the sodium levels for the term "healthy." Comments

<sup>1</sup> Under § 101.13(h)(1) (21 CFR 101.13(h)(1)), individual foods containing more than 480 mg sodium per reference amount, per labeled serving size, or per 50 g (if the reference amount is 30 g or less or 2 tablespoons or less) must bear a label statement referring consumers to information about the amount of sodium in the food. Such nutrient disclosures are required when a food contains more than certain amounts of total fat, saturated fat, sodium, and cholesterol and that food bears a nutrient content claim. *Id.*, see section 403(r)(2)(B) of the act. The agency developed disclosure levels based on dietary guidelines and taking into account the significance of the food in the total daily diet, based on daily reference values for total fat, saturated fat, cholesterol, and sodium (58 FR 2302 at 2307, January 6, 1993).

suggesting that the agency should amend the “healthy” definition were asked to address what the amended regulation should require to ensure that the term “healthy” could appear on a significant number of foods, without being “so broadly defined as to lose its value in highlighting foods that are useful in constructing a diet that is consistent with dietary guidelines” (62 FR 67771 at 67772). FDA asked those who believed the second-tier sodium requirements were appropriate and should not be changed to provide data demonstrating that the second-tier “healthy” definition was not so restrictive as to effectively preclude the use of the term.

In the ANPRM, FDA requested data or evidence on what would happen to the use of the term “healthy” in the marketplace if the second-tier sodium levels were to take effect. In addition, the agency asked how many “healthy” products would be eliminated if the second-tier sodium levels were to take effect and whether there would be other impacts on the number of consumer choices. The agency also asked for data regarding the technological feasibility of reducing the sodium content of individual foods, including raw, single-ingredient seafood and game meats, to 360 mg per reference amount and of reducing the sodium content of meals and main dishes to 480 mg sodium per serving size.

FDA also requested information and views on consumer acceptance of foods at the second-tier sodium levels. The agency further requested information about the availability or lack of availability of acceptable sodium substitutes, the difficulties in manufacturing different lines of food products with lowered sodium levels, and the impact of these lower sodium levels on the shelf-life stability and safety of the food. FDA also requested comments on other approaches to reducing the amount of sodium in foods that bear the term “healthy” (62 FR 67771 at 67773 and 67774).

If comments responding to the ANPRM revealed agreement that there were technological hurdles that could not be overcome for all foods or certain types of food, the agency stated that it would be interested in exploring different options for maximizing the public health gains expected from reducing dietary sodium levels. The agency identified four options. First, the agency could make no changes in the stayed rule, and the second-tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii) would become effective at the end of the stay period. This was identified as the default option if industry failed to

provide evidence, data, or arguments that supported amending the rule. Second, as requested by the petitioner, FDA could propose to amend the definition of “healthy” to make the first-tier sodium levels the qualifying levels for all food products, and to delete in their entirety the second-tier sodium levels. Third, the agency could continue the stay based on data and information submitted in response to the ANPRM suggesting technological advancements could be made but would require more time. Fourth, the agency could reconsider the second-tier sodium levels and create new levels based on other factors such as percentile reductions based on market basket norms (62 FR 67771 at 67774).

In response to requests for an extension to coincide with the end of the comment period for the U.S. Department of Agriculture’s (USDA’s) interim final rule on the use of “healthy” on the label or labeling of meat and poultry products (63 FR 7279, February 13, 1998), FDA extended the closing date of the comment period for the ANPRM, from March 16, 1998, to May 19, 1998 (63 FR 13154, March 18, 1998).

In the **Federal Register** of March 16, 1999 (64 FR 12886), FDA published a final rule extending the partial stay of the second-tier sodium requirements in § 101.65 until January 1, 2003. The agency noted that it took this action to provide time for: (1) FDA to reevaluate the supporting and opposing information received in response to the ConAgra petition, (2) the agency to conduct any necessary rulemaking on the sodium limits for the term “healthy,” and (3) companies to respond to any changes that may result from agency rulemaking. On May 8, 2002 (67 FR 30795), FDA issued another final rule to extend the partial stay of the second-tier sodium requirements in § 101.65 until January 1, 2006.

While the partial stay was pending, USDA and the Department of Health and Human Services jointly published the “Dietary Guidelines for Americans 2000” (dietary guidelines) (Ref. 1). This report provides recommendations for nutrition and dietary guidelines for the general public and suggests a diet with a moderate sodium intake, not exceeding 2,400 mg per day. The health concerns relating to high salt intake are high blood pressure and loss of calcium from bones, which may lead to risk of osteoporosis and bone fractures (Ref. 1).

## II. Summary of Comments From the ANPRM

FDA received 22 responses, each containing one or more comments, to the December 30, 1997, ANPRM.

Most of the comments stated that the requirements for the use of the term “healthy” should be amended and presented evidence to persuade the agency to change the sodium levels. The comments provided information that a large number of meal and main dish products currently labeled as “healthy” would not be able to meet the “healthy” definition should the second-tier sodium levels take effect. The comments also stated that technological advances have not yet yielded an acceptable salt substitute.

Several comments discussed the possibility of the agency engaging in rulemaking to set new sodium levels. For instance, a few comments suggested using a sodium level based on a percentile reduction from the market-basket norm (e.g., 25 percent less sodium than otherwise comparable products that are currently on the market). The levels could be established for each food category or for those particular food items having difficulty meeting the second-tier sodium levels. One comment objected to “relaxing” the standards and suggested even tighter regulation in the interest of public health (200 mg for individual foods and 400 mg for meal products).

A few comments stated that the second-tier sodium levels were reasonable and should no longer be delayed. Evidence presented in these comments consisted of: (1) Information suggesting that manufacturers could conform to the second-tier sodium levels without presenting food safety concerns, and (2) summary lists of products that would remain in the marketplace if the second-tier sodium levels took effect.

The remaining comments did not directly address the issue of whether FDA should amend the sodium levels, but, rather, provided general information or opinions regarding sodium levels. For example, one such comment stated that there are health risks associated with a low-sodium diet.

FDA used information provided in the comments, along with information the agency gathered through an independent data analysis, to determine its proposed action.

## III. Proposed Action

### A. Introduction

The agency established a definition for the term “healthy” as an implied nutrient content claim (59 FR 24232).

The fundamental purpose of a “healthy” claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines, which suggest that daily sodium intake not exceed 2,400 mg (Ref. 1). To assist consumers in constructing such a diet, a reasonable number of “healthy” foods should be available in the marketplace.

FDA stated in the ANPRM that its goal was to establish sodium levels for the definition of “healthy” that are not so restrictive as to preclude the use of the term “healthy,” and not so broadly defined as to cause the term to lose its value in identifying useful products for constructing a healthy diet (62 FR 67771 at 67772).

To assess the number of “healthy” products in the marketplace, FDA conducted a marketplace data analysis (Ref. 2) using information from the Information Resources, Inc. (IRI) InfoScan database. The IRI InfoScan database contains dollar and sales information for food and dietary supplement products. InfoScan includes information collected weekly from a selected group of grocery, drug, and mass merchandiser stores across the continental United States with annual sales of \$2 million and above (sample store data)—more than 32,000 retail establishments. The retail stores are statistically selected, and the database contains sales data for all products in these retail stores that are scanned (i.e., sold) at check out. IRI applies projection factors to the sample store data to estimate total sales in the continental United States from stores that have annual sales of \$2 million and above. Using the IRI InfoScan database, FDA estimated the number of “healthy” brands and “healthy” products in the marketplace during 1993 to 1999.

In the following discussion of the marketplace data analysis, the term “brands” refers to brand names (not manufacturers) in the IRI InfoScan database (e.g., Healthy Choice, Health Valley, Healthline), while the term “products” refers to the different items (i.e., separate Universal Product Codes) sold under that brand name (e.g., raisin bran versus corn flakes; 12-ounces (oz) package versus 16-oz package) (Ref. 2).

#### *B. Individual Foods*

##### *1. Conventional Foods*

In the marketplace data analysis of “healthy” individual foods, the agency estimated the total number of “healthy” products and brands available in 1993, in 1999, and any time in the timeframe from 1993 to 1999. The agency also

estimated the number of “healthy” individual foods for specific food categories. FDA does not have any data to determine either the number of “healthy” products or the pace of increase in the availability of “healthy” products prior to 1993. When compiling the marketplace data analysis, the agency considered all conventional foods that did not meet the meal or main dish definition in § 101.13(l) and (m) (including soups, salads (e.g., precut in a bag, prepared refrigerated salads), and single-ingredient seafood and game meats) to be individual foods. FDA considered dietary supplements separately using a different database. Dietary supplements are discussed in section III. B.2 of this document.

FDA estimated that in 1999 the marketplace had 872 “healthy” individual food products available to the consumer, compared to 842 such products available in 1993 (Ref. 2). There was also an increase in the number of “healthy” brands for individual foods in the marketplace from 1993 to 1999. In 1993, only 50 brands carried a “healthy” product, while 69 brands were available in 1999.

Considering that the 1993 figures are representative of the marketplace prior to the 1994 final rule defining “healthy,” the increase in “healthy” products shows that, in addition to manufacturers being able to comply with the definition established in 1994, they have also been able to develop additional “healthy” products. Manufacturers have increased the number of available “healthy” brands as well as the number of available “healthy” products at or below the first-tier sodium level.

There has been an increase in the number of “healthy” individual food products in many of the specific food categories defined by IRI (Ref. 2). For example, in the IRI category of “Salty Snacks” (e.g., pretzels, potato chips), there were 18 available “healthy” products in 1993 and 46 in 1999, with 3 “healthy” brands available in 1993 and 5 in 1999. For popcorn products identified in the IRI category of “Popcorn/Popcorn Oil,” no “healthy” products existed in 1993, but in 1999 there were 10 “healthy” products and 2 “healthy” brands in the marketplace. Similarly, in the IRI category “Fresh Breads & Rolls,” 21 “healthy” products and 5 “healthy” brands were on the market in 1993, while in 1999, 64 “healthy” products and 9 brands were available. Increases can also be seen in the IRI category of “FZ [Frozen] Seafood”; 14 “healthy” products were available in 1993, while 22 were available to consumers in 1999, with 3

“healthy” brands in both 1993 and 1999. These are only a few examples of increases in the number of “healthy” individual food products available to the consumer.

Not all food categories, however, had an increase in the number of “healthy” products from 1993 to 1999. For instance, foods in the IRI categories “Cold Cereal,” “Cookies,” “Dried Fruit,” “Salad Dressings—SS” (where SS stands for shelf stable), “Sauce,” and “Carbonated Beverages” saw a drop in the number of “healthy” products available from 1993 to 1999 (Ref. 2). For food categories such as cold cereal, salad dressing, and sauces, sodium may have been a factor in the decrease in the number of products available from 1993 to 1999 because the sodium levels in these products cover a very wide range, and some exceed the first-tier requirement for products labeled as “healthy” (Ref. 3). However, based on typical sodium levels for other food categories, such as cookies, dried fruit, and carbonated beverages, it is unlikely that sodium was responsible for the decrease in the number of these “healthy” products in the marketplace because typical sodium levels are below both the first- and second-tier sodium levels (Ref. 3).

In addition, certain food categories generally contain little sodium. Foods such as fish, fruit juices, hot cereals, rice, vegetables, pastas, and yogurt typically have considerably less than 360 mg sodium per reference amount and per serving size (Ref. 3). For most of these foods, there was an increase or no change in the number of brands and products available in 1999 compared to 1993 (Ref. 2). There was a decrease in the number of vegetable and pasta products labeled “healthy;” however, there is no reason to believe that this decrease was due to the sodium content. Because these categories of food generally contain little sodium, the proposed second-tier sodium level is unlikely to have an impact on the number of “healthy” products in the marketplace.

The agency also evaluated data from the 1997 Food Label and Package Survey (FLAPS) (Ref. 4), which represents data collected in 1997 from a limited number of product brands in specific food categories. The agency reviewed this database because it includes data that were not available in the marketplace data analysis, including information on claims and other information included on product labels. For example, FDA found a number of “healthy” claims on individual foods (Ref. 4), such as “Healthy real egg product” and “Apple sauce is a

delicious and healthy fruit product, which contains no fat, very low sodium, and no cholesterol." Such statements are implied nutrient content claims for "healthy" that the marketplace data analysis did not identify because the term "healthy" was not part of the brand name of the product. This leads FDA to believe that there are individual foods in the market place bearing "healthy" claims in addition to those identified in the marketplace data analysis. As some "healthy" claims are not part of the brand name of the product and, therefore, were not captured in the marketplace data analysis, it is likely that the number of "healthy" individual foods included in that analysis underestimates the number of individual food products bearing "healthy" claims.

The agency notes that individual foods with reference amounts on the lower end of the scale are also less likely to be affected by adoption of the second-tier sodium level because they are able to claim the same 360 mg sodium level for a "healthy" product as other individual foods with larger reference amounts. For example, bread or rolls have a reference amount of 50 g (§ 101.12(b) (21 CFR 101.12(b)), table 2, "Bakery products: Breads (excluding sweet quick type), rolls"). A 50 g serving of bread or rolls typically contains less than 360 mg sodium (Ref. 3) and would meet the second-tier criterion. Contrast that with individual foods such as pasta or potato salad, which have a reference amount of 140 g (§ 101.12(b), table 2 "Salads: Pasta or potato salad"). Assuming other aspects of the "healthy" definition are met, 140 g of pasta or potato salad must contain no more than 360 mg sodium to be considered "healthy," although the reference amount for pasta or potato salad (140 g) is almost three times that of bread or rolls (50 g). Many other individual foods are similar to the bread and rolls, having a reference amount on the lower end of the scale, which allows those products more flexibility in their sodium level.

Additionally, the agency believes that some individual foods may be close to meeting the second-tier sodium level. If the second-tier sodium level goes into effect, manufacturers may choose to reformulate such products in order to retain a "healthy" claim.

The ConAgra petition and other comments identified a few specific categories of individual foods for which the ability to make "healthy" claims could be negatively affected by permitting the second-tier sodium levels to take effect (e.g., soups, cheeses, frankfurters, and luncheon meats). FDA examined the marketplace data analysis

for these specific food categories (Ref. 2).

The total number of "healthy" wet and dry soup products available in the marketplace increased during 1993 through 1999. In 1993, 104 "healthy" soup products were on the market. In 1999, over 20 more products were available, for a total of 126 "healthy" soup products in 1999. The number of "healthy" brands remained steady at six in both 1993 and 1999.

The petitioner indicated that its "healthy" soup products would not be able to meet the second-tier sodium level. The petitioner stated that it had expended numerous resources (e.g., consulting with experts in the field of food technology and conducting research and development programs with flavor companies) and was not able to find a satisfactory salt replacement for its "healthy" line of soups.

On the other hand, a comment by a major manufacturer of soups claimed that it has been able to reduce the sodium levels in its "healthy" soups and is currently able to meet the second-tier sodium level for "healthy" individual foods. The comment from this major soup manufacturer indicated that it was able to reformulate its "healthy" soup product line by modifying the flavor system with ingredient changes on a product by product basis. The comment also noted that reducing sodium in a product is technically difficult but not unsolvable and that the flavor profile of a product can be manipulated so that it maintains consumer appeal.

Because one major soup manufacturer has been able to develop a "healthy" soup line that meets the second-tier sodium level for "healthy" individual foods, FDA tentatively concludes that it is technologically feasible to produce a "healthy" soup product that meets the second-tier sodium level and is palatable to consumers. The petitioner also stated that cheese might not be able to meet the second-tier "healthy" sodium requirement because salt is required in the manufacturing process and cannot be reduced without jeopardizing taste and texture. The petitioner also contended that if FDA permits the second-tier sodium level to take effect for individual foods, there will be no "healthy" version of cheese in the marketplace.

Another comment stated that if it is not possible to manufacture a "healthy" cheese, then no exception should be made, and cheese products should be removed from the "healthy" marketplace until manufacturers are capable of producing a cheese that meets the "healthy" definition.

The petitioner's comments regarding cheese are reinforced by the trend seen by FDA in its marketplace data analysis (Ref. 2). For example, there has been a general decline in the number of "healthy" cheeses in the marketplace. In 1993, before the final rule defining "healthy" was issued, there were a total of 60 "healthy" cheese products with 3 different brands on the market; however, in 1999, the numbers dropped to 32 products with only 1 brand in the marketplace. Furthermore, in Spring 2001, FDA staff made an informal telephone inquiry to the customer service center of the only manufacturer of "healthy" cheese identified in the marketplace data analysis for 1999 (Ref. 5). The manufacturer indicated that its "healthy" line of cheese had been discontinued. To the best of the agency's knowledge, no new manufacturer has entered the "healthy" cheese market.

FDA agrees that cheese generally requires salt in the manufacturing process. Cheese is made from the coagulation of milk into curds and whey. The whey is drained off and salt (sodium chloride) is typically added to the curd to control microbial growth and enzyme activity, assist in curd synthesis (whey expression), and directly cause changes in cheese proteins that will influence cheese texture (Ref. 6). The agency requests comments on whether salt is the limiting element in achieving a "healthy" cheese and whether salt can be removed from the cheese-making process.

FDA notes that "healthy" cheeses may have been removed from the marketplace for reasons other than the sodium requirement. Some "healthy" cheeses (e.g., light mozzarella cheeses) were able to meet the proposed second-tier sodium level for "healthy" individual foods; nonetheless, those products were removed from the marketplace (Ref. 5). In addition to sodium, cheese also typically contains fat and saturated fat, which have been identified as nutrients to limit when constructing a "healthy" diet (Ref. 1). Because the "healthy" claim sets limits on all three nutrients, the multiple requirements may be the reason why "healthy" cheeses are no longer in the marketplace. FDA requests comments that would help clarify whether it is the sodium limit, the fat or saturated fat limits, the combination of limits, or some other factor or factors that have resulted in manufacturers discontinuing the manufacture and marketing of "healthy" cheeses.

Further, the agency is not persuaded that it is necessary to provide for

“healthy” cheese since the lack of a “healthy” cheese product is not likely to prevent consumers from constructing a diet consistent with dietary guidelines. Although cheese contributes calcium to the diet (Ref. 1), consumers can obtain their reference daily intake (RDI) of calcium from many other sources such as low-fat milk, yogurt, and dark-green leafy vegetables, to name a few.

For consumers who choose to eat cheese, there are alternative cheese products such as “reduced fat” or “reduced sodium” cheeses. These claims accurately describe the specific attributes of the product without claiming that it conforms to the requirements for “healthy.”

FDA also is concerned that treating cheese differently from other foods could be misleading to consumers trying to construct a healthy diet. Cheese has a small reference amount (30 g) (§ 101.12(b), table 2, “Dairy Products and Substitutes: Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread”), and therefore, more than one serving can be consumed easily. In general, approximately 32 g to 46 g of cheese is consumed per eating occasion (Ref. 7). Because the actual amount consumed is typically larger than the reference amount (30 g), it appears that consumers will be better served if the second-tier sodium level applies to all foods, including cheese. Applying the second-tier sodium level to cheese will help maintain a reasonable sodium intake even for those people who consume larger amounts of cheese.

However, FDA invites comments on whether having no “healthy” cheeses may have a negative impact on consumers, and if so, whether the agency could establish a reasonable alternative sodium requirement for “healthy” cheese. Alternative methods might include: (1) Leaving cheese at the current first-tier sodium level for “healthy” individual foods (480 mg) or (2) establishing “healthy” sodium levels based on a percent reduction of market-basket norms.

The first alternative of leaving cheese at the current first-tier sodium level for “healthy” individual foods may encourage cheese manufacturers to reenter the marketplace, since they would no longer have to face uncertainty as to whether the sodium level would be reduced to the second-tier level. The marketplace data analysis showed that there were 32 “healthy” cheese products in 1999, demonstrating that manufacturers were capable of producing a “healthy” cheese at the current first-tier sodium level.

The second alternative of establishing a “healthy” sodium level based on a market-basket norm may not be practical for all individual foods but may be appropriate for cheese because of its special manufacturing process. To consider both alternatives, it would be helpful to have additional information, such as: (1) The sodium levels for various cheeses currently in the marketplace that do not bear the term “healthy” (i.e., the current market-basket norm) and what might be an achievable percent reduction for sodium from that market-basket norm; (2) the impact that exempting cheese, not exempting cheese, or establishing an alternative sodium level would have on diets; (3) the minimum levels of sodium that can be achieved in the production of an acceptable cheese product; (4) the technology available to reduce sodium levels in cheese products; and (5) the extent to which salt (sodium chloride) is required in the cheese-making process.

Comments received in response to the ANPRM also indicated that frankfurters and luncheon meat may have difficulty meeting the second-tier sodium level of the “healthy” definition. However, those products fall outside FDA’s jurisdiction, as they are regulated by USDA; therefore, they are not addressed in this proposal.

Another issue raised by the petitioner was the role of salt as a preservative in refrigerated foods, particularly meat and poultry products, because the petitioner contended that refrigeration alone cannot be relied upon to ensure food safety. However, a comment stated that the difference between the first-tier (480 mg) and the second-tier (360 mg) sodium levels is insignificant with respect to food safety. The comment noted that sodium does not protect against microbiological contamination in processed meats and that no one factor is responsible for product safety.

Again, since meat and poultry fall outside FDA’s jurisdiction, they will not be addressed in this rulemaking. The agency requests comments on whether sodium levels of 360 to 480 mg are protective and play a role in food safety for foods that FDA regulates; whether changing from the first- to the second-tier sodium level would negatively impact food safety; and what other preservation methods could be used to ensure food safety in conjunction with lower sodium levels.

Based on the data summarized, it appears that: (1) A reasonable number of “healthy” individual food products were available in the marketplace from 1993 through 1999; (2) in many food categories there has been an increase in the number of “healthy” products and

brands; and (3) many “healthy” individual foods, such as those with reference amounts at the lower end of the scale or those that typically contain limited amounts of sodium, would remain unaffected by the proposed change to the second-tier sodium level for individual foods. Therefore, with the possible exception of cheeses, the overall impact of permitting the second-tier sodium level to take effect for individual foods appears to be limited to minor reductions in the number of “healthy” products in some food categories.

Accordingly, the agency tentatively concludes that the second-tier sodium level is the appropriate sodium requirement for the “healthy” definition for individual foods. The agency believes the second-tier sodium level provides a meaningful definition of “healthy” that will enable consumers to construct a diet that is consistent with current dietary guidelines but is not so narrowly defined as to disqualify many foods that are recommended to be in the diet (59 FR 24232 at 24240).

Therefore, the agency is proposing not to amend the second-tier “healthy” sodium level of 360 mg for individual foods in current § 101.65(d)(2)(ii)(C)(1) and (d)(2)(ii)(C)(2), and (d)(3)(ii)(C)(1) and (d)(3)(ii)(C)(2). These paragraphs are being revised in format, however, as discussed in section III. F of this document. The second-tier sodium level for individual foods is to take effect at the end of the stay period, January 1, 2006 (67 FR 30795).

The agency is requesting comments and information on the potential impact of the second-tier sodium level on specific individual food categories. In particular, FDA is seeking information on the range of sodium content in food categories and the proportion of products that contain sodium at or below the first- and second-tier levels of current § 101.65.

## 2. Dietary Supplements

Dietary supplements, like other individual foods, must meet all of the requirements in § 101.65(d)(2) to make “healthy” claims. FDA has evaluated data for dietary supplements and tentatively concludes that permitting the second-tier sodium level to go into effect is unlikely to reduce the availability of “healthy” dietary supplements. The agency assessed the prevalence of dietary supplement products that contain salt or sodium and are labeled as “healthy.” The agency used a database developed by Research Triangle Institute (RTI) (Ref. 8), which includes detailed information on approximately 3,000 dietary supplement

products collected between November 1999 and February 2000, including information from labels of products purchased from retail establishments and information taken from mail-order catalogs and Internet sites. In selecting dietary supplement products, RTI used the definition of "dietary supplement" from the Dietary Supplement Health and Education Act of 1994 (Public Law 103-417), which includes, among other things, vitamins, minerals, herbs and other botanicals, and amino acids (section 201(ff) of the act (21 U.S.C. 321(ff))). RTI included only information available to consumers at the point-of-sale.

The RTI sampling procedure was designed to include the maximum number of different products and different ingredients, which led to a relatively greater variety of products than would be representative of consumer purchase patterns. In order to get as many products as possible with different characteristics, RTI over-sampled health food stores. This led to an over-sample of herbals and botanicals, which, according to the database, are more likely to contain sodium. Thus, the design of the survey (e.g., how the products were sampled) would be likely to lead to an overestimate of the percentage of dietary supplements that contain sodium.

FDA recognizes that the RTI database cannot be used to make precise, quantitative estimates of dietary supplement characteristics; nevertheless, in the absence of other available data, FDA used these data to estimate the proportion of dietary supplement products that might be affected by permitting the second-tier sodium requirements to take effect for the term "healthy." FDA found these data useful as they allow for a conservative estimate of the impact of the proposed rule on dietary supplement products, because it is likely that a smaller proportion of products will be impacted than the proportion calculated under this assessment. FDA requests comments on this assessment of dietary supplement products that may contain sodium and welcomes any additional available data concerning dietary supplements.

To estimate the proportion of dietary supplement products in this dataset that contain sodium, FDA reviewed the ingredient information in the RTI database, which includes information on the first 30 ingredients contained in the product. The agency searched for ingredients containing either the term "salt" (sodium chloride), the most common source of sodium in foods, or the term "sodium" (e.g., sodium

benzoate). This process would not have identified ingredients containing other sources of sodium (i.e., ingredients that include sodium-containing components that do not include sodium in their name). FDA identified 133 dietary supplement products in this dataset (4 percent) containing the terms "sodium" or "salt" in one or more of the first 30 ingredients.

To estimate the proportion of dietary supplement products in this dataset that may contain sodium and also bear a claim for "healthy," FDA reviewed the database for brand names, product names, and claims on the 133 dietary supplement products. The agency found 1 product with the term "health" in the brand name, 1 product with the term "health" in the product name and also in the product claim, and 32 products with claims containing the terms "health" or "healthy." Most of the claims on the products were structure/function claims under 21 CFR 101.93(f) (e.g., "Helps promote bone health") or health claims under 21 CFR 101.14 (e.g., "Enough calcium helps maintain good bone health and reduce the risk of osteoporosis"); such claims would not be considered "healthy" claims under § 101.65(d). FDA did, however, identify 11 products in this dataset (0.4 percent) bearing "healthy" claims under § 101.65(d) either as part of the brand or product name or as a separate claim on the product (Ref. 8). Since this dataset over-sampled products that are more likely to contain sodium, it is likely that less than one percent of dietary supplement products would potentially be affected by requiring individual foods bearing the claim "healthy" to meet the proposed, second-tier sodium requirement.

In addition to the relatively small proportion of dietary supplement products overall that contain sodium and bear "healthy" claims, judging from our sample of 11 products in this dataset, the amount of sodium contained in these dietary supplement products is probably quite limited for a variety of reasons. Since ingredients are listed on product labels in descending order of predominance by weight (21 CFR 101.4), the amount of sodium in dietary supplement products is likely to be small because the sodium-containing ingredients tend to be minor ingredients (Ref. 8). Furthermore, dietary supplement products tend to have small serving sizes (e.g., pills, capsules, packets, teaspoons).

In addition, only a small proportion of most sodium-containing dietary supplement ingredients is actually sodium. For example, salt (sodium chloride) is the ingredient with the

highest proportion of sodium, about 40 percent. The agency calculated the percentage of sodium for the other sodium-containing ingredients about which the agency had sufficient information, and these other ingredients contain a significantly smaller proportion of sodium, varying from around 12 to 27 percent (Ref. 8). Thus, dietary supplements are likely to contain limited amounts of sodium because the sodium-containing ingredients themselves contain limited amounts of sodium.

An example may help to illustrate how the two factors discussed work in tandem to limit the amount of sodium in dietary supplement products. Only one of the 11 products bearing a healthy claim listed salt as an ingredient. This product lists salt as the 14th ingredient in order of predominance. Thus, the amount of sodium in that particular dietary supplement product is likely to be small since it is only 40 percent of a very minor ingredient.

Also, unlike conventional food products that use salt to improve taste, dietary supplement products are taken to supplement the diet and are not generally consumed for their taste. Most dietary supplement products are in pill, tablet, or capsule form (Ref. 8) and are swallowed without chewing. Therefore, since taste is not a factor for most of these products, manufacturers selecting ingredients for their dietary supplement products can easily avoid sodium-containing ingredients if they are trying to limit the sodium content in order to make "healthy" claims.

Thus, given the foregoing information and observations based on the RTI data sample, FDA does not anticipate that the sodium content of dietary supplement products will have an impact on their ability to qualify for "healthy" claims. Furthermore, the agency received no comments to the ANPRM from dietary supplement manufacturers indicating that dietary supplement products currently making "healthy" claims would be affected. Thus, FDA does not believe that changing the sodium content requirement for individual foods bearing "healthy" claims will adversely affect dietary supplement manufacturers wishing to make such claims. The agency requests comments on whether its assessment regarding dietary supplement products is accurate and whether or not the availability of dietary supplement products bearing a "healthy" claim would be adversely affected by this rulemaking. FDA requests specific information on such products, including the numbers and types of products affected, the current

level of sodium in the products, and the types of “healthy” claims that are being made.

### C. Meal and Main Dish Products

For purposes of this section, meal and main dish products, which are defined separately in § 101.13(l) and (m), will be considered together. This is consistent with earlier treatment in the proposed rule, the final rule, the partial stays, and the ANPRM.

To assess the status of meal and main dish products, the agency separated the data on meal and main dish products from the data on other products in the marketplace data analysis. When determining the number of products and brands that fall within the meal and main dish category, the agency included chili with meal or main dish products. In performing this assessment, the agency considered three categories: (1) Frozen meals and main dishes, (2) refrigerated and shelf-stable meals and main dishes, and (3) chili. FDA identified 148 meal and main dish products labeled “healthy” among 10 brands in the IRI analysis (Ref. 2). The 1997 FLAPS did not identify any meals or main dishes that used a “healthy” claim but were not from a “healthy” brand (Ref. 4).

The petitioner stated that a number of “healthy” meal and main dish products would “disappear” if the second-tier sodium levels were to take effect for meal and main dish products. The petitioner further indicated that it would not be able to produce many meal or main dish products that meet the second-tier sodium level and that are palatable. The petitioner also commented that some weight-control meal and main dish products are substantially higher in sodium than the second-tier level established for “healthy” meal and main dish products.

The petitioner provided the agency with data regarding how the current first-tier sodium levels for the “healthy” definition aid the consumer in achieving a diet that is consistent with dietary guidelines. The data included a sample menu of an average adult’s daily consumption of “healthy” individual foods and meal and main dish products at the current first-tier sodium levels (Ref. 9). The sample menu demonstrated that an adult using “healthy” as a guidepost could obtain a diet with a sodium level close to the recommended daily sodium intake (Ref. 1).

In contrast, another comment supported permitting the second-tier sodium level for “healthy” meal and main dish products to take effect and claimed that the lower sodium level is attainable. However, that comment did

not come from a firm that produces “healthy” meal or main dish products. In addition, the comment did not provide any basis for concluding that a reasonable number of “healthy” meal and main dish products would remain in the marketplace if the second-tier sodium levels were to take effect for meal and main dish products.

Based on the marketplace data analysis, the agency found that there were a limited number of “healthy” meal and main dish products that met the current first-tier sodium level. The agency further found a general decline in the number of meal and main dish products available in 1999 compared to 1993 (Ref. 2).

The number of “healthy” frozen meals and main dishes decreased from 177 products in 1993 to 119 products in 1999. During 1993 through 1999, 272 “healthy” frozen meal and main dish products were placed on the market, with less than half surviving until 1999. Similarly, the number of “healthy” frozen meal or main dish product brands has also decreased. In 1993, there were nine “healthy” brands available, and only six brands remained in 1999.

The number of “healthy” shelf-stable or refrigerated meal and main dish products also has decreased, with 23 products available in 1993 and only 11 products in 1999 (Ref. 2). During 1993 through 1999, 33 “healthy” shelf-stable and refrigerated meals and main dish products were introduced into the market, with only 30 percent of those products surviving in 1999. The number of brands marketing a “healthy” shelf-stable or refrigerated meal or main dish product has dropped slightly, with five brands available in 1993, and four brands in 1999. Only “healthy” chili products have increased in number from 10 in 1993 to 18 in 1999, and from 1 to 2 brands in that same timeframe.

Overall, the number of available meal and main dish products (including frozen, shelf-stable, refrigerated, and chili products) decreased by 30 percent, from 210 products in 1993 to 148 products in 1999 (Ref. 2). This appears to indicate that providing consumers with a palatable “healthy” product at the current, first-tier sodium level is difficult.

The limited number of “healthy” meal and main dish products affects FDA’s goal to provide a definition for “healthy” that permits consumers access to a reasonable number of products that bear the “healthy” claim. If FDA were to allow the second-tier sodium level for “healthy” meal and main dish products to take effect, there would likely be an even greater

reduction in the number of available “healthy” meal and main dish products in the marketplace. Furthermore, some manufacturers of “healthy” meal and main dish products might choose to limit only fat or calorie levels and change to “lean,” “low calorie,” or “low fat” claims. Although those claims do provide some assistance to consumers who are trying to construct a diet consistent with dietary guidelines, there are additional nutritional benefits in products bearing a “healthy” claim. “Healthy” meal and main dish products, in addition to meeting the sodium limit, also meet the definition of “low” for fat and saturated fat; contain no more than 90 mg of cholesterol per serving size, and contain at least 10 percent of the RDI or daily reference value per serving size of two (for main dish products) or three (for meal products) of the following nutrients: Vitamin A, vitamin C, calcium, iron, protein, and fiber (§ 101.65(d)).

Moreover, FDA finds the petitioner’s comment that a number of meal and main dish products would “disappear” to be persuasive because the petitioner is one of only a few manufacturers currently producing “healthy” meal and main dish products. The marketplace data analysis for “healthy” meal and main dish products and brands showed that there were a limited number of “healthy” meal and main dish manufacturers, with one manufacturer producing most of the “healthy” meal and main dish products. In 1999, most of the meal and main dish products available were frozen dinners and entrées. There were only 6 “healthy” brands of frozen meal and main dish products, and 5 of the brands comprised only 16 percent of the products available (Ref. 2). The remaining 84 percent of “healthy” meal and main dish products were manufactured by the petitioner. Between 1993 and 1999, there were 10 brands marketed by firms other than the petitioner. Five brands that were available for sale in 1993 had completely disappeared from the market by 1999; two brands had significantly fewer products for sale; two brands that were not available in 1993 offered only a few products in 1999; and one brand had more products for sale in 1999 than in 1993. The petitioner also had more “healthy” products for sale in 1999 than in 1993. Considering the petitioner’s expertise in the “healthy” frozen meal and main dish market, and the trends seen in the marketplace, FDA believes that the petitioner raised valid concerns about the second-tier sodium level for meal and main dish products.

Furthermore, the sodium content of the sample menu provided by the



petitioner in support of retaining the first-tier sodium levels is close to the recommended daily sodium intake set forth in the dietary guidelines (Ref. 9). FDA believes that minor adjustments, such as the lower sodium level the agency is proposing for "healthy" individual foods, would be sufficient to bring such a menu within dietary guidelines.

The 1997 FLAPS data (Ref. 4) did not contain any additional "healthy" claims for meal and main dish products that were not already identified in the marketplace data analysis. This further supports the contention that there are a limited number of "healthy" meal and main dish products in the marketplace.

Meal and main dish products make a major contribution to the total daily diet, and FDA believes that sodium requirements for these products should reflect this contribution, while remaining consistent with current dietary guidelines. For example, under § 101.13(l), a meal is defined as weighing at least 10 oz per labeled serving and containing not less than three-40 g portions of food, or combinations of foods, from two or more of the four food groups: (1) Bread, cereal, rice, and pasta; (2) fruits and vegetables; (3) milk, yogurt, and cheese; and (4) meat, poultry, fish, dry beans, eggs, and nuts. Under the first-tier sodium requirement, a "healthy" meal must fall within the 600 mg sodium level per serving size of not less than 10 oz (282 g), or approximately 2.1 mg sodium per g of food. A "healthy" main dish, under § 101.13(m), must contain not less than 40 g of food, or combinations of foods, from each of at least two of the four food groups, and must contain 600 mg or less sodium per serving size of 6 oz (170 g), or approximately 3.5 mg sodium per g of food.

By contrast, the first-tier sodium level for "healthy" meal and main dish products is more stringent than the sodium level of a meal consisting of "healthy" individual foods at the second-tier sodium level. For example, both fresh or frozen vegetables and cooked fish/shellfish have reference amounts of 85 g (§ 101.12(b), table 2, "Vegetables: All other vegetables without sauce: fresh, canned, or frozen" and "Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes: Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake"). Prepared fried potatoes have a reference amount of 70 g (§ 101.12(b), table 2, "Potatoes and Sweet Potatoes/Yams: French fries, hash browns, skins, or pancakes"). Under the second-tier sodium definition of "healthy,"

individual foods are limited to 360 mg sodium per reference amount and per serving size. The sodium levels under these requirements would be approximately 4.2 mg sodium per g of fish or vegetables and approximately 5.1 mg sodium per g of potato. These levels are more than 200 percent higher than the sodium level that "healthy" meals are required to meet at the first-tier sodium level (2.1 mg sodium per g of food) and 120 percent higher than the first-tier sodium level for "healthy" main dish products (3.5 mg sodium per g of food). These examples demonstrate that the first-tier sodium level for "healthy" meal and main dish products is already more stringent than the second-tier sodium level proposed for "healthy" individual foods typically included in such meals and main dishes.

Furthermore, the first-tier sodium level proposed for "healthy" meal and main dish products is proportionate to and adequately reflects their contribution to the total daily diet while remaining consistent with current dietary guidelines. If each meal or main dish product has a maximum of 600 mg sodium and if one meal or main dish product is consumed at each of three meals during a typical day, then this accounts for a total of 1,800 mg sodium from meal and main dish products. This is consistent with previous agency assumptions that daily food consumption patterns include three meals and a snack with about 25 percent of the daily intake contributed by each (final rule on nutrient content claims (58 FR 2302 at 2380, January 6, 1993)). The 1,800 mg sodium level is well below the suggested 2,400 mg recommendation (Ref. 1) and allows for flexibility in the rest of the daily diet (i.e., the snack).

A number of comments to the ANPRM addressed whether there is an acceptable salt substitute that could be used to replace salt in meal and main dish products. Most of those comments indicated that currently it is not technologically feasible to manufacture a "healthy" meal or main dish product that uses a salt substitute to help meet the second-tier sodium level. Many flavor manufacturers stated that although they have been working towards a flavor profile to replicate salt, an acceptable salt substitute is not yet available. The comments stated that some of the salt substitutes currently available are ammonium salt and potassium chloride. The comments further stated that these are not effective salt substitutes because they leave an off or bitter aftertaste and require a masking of that aftertaste that is not always

successful. One flavor manufacturer asserted that it is not necessary to change the sodium requirements for the definition of "healthy" because this manufacturer had created a salt substitute that is acceptable for use in most processed foods. However, the petitioner described working with that manufacturer and using that salt substitute to try to reduce sodium in their products (e.g., frozen entrées) without success.

It appears that technological advances have not yet yielded an acceptable salt substitute that would allow meal and main dish products to meet the second-tier sodium level for the definition of "healthy." Furthermore, the second-tier sodium levels have been stayed several times to give manufacturers more time to develop alternatives. Because of the apparent difficulty of producing an acceptable salt substitute, FDA is no longer convinced that providing additional time will lead to the development in the near future of a salt substitute that is acceptable to manufacturers and palatable to consumers.

FDA tentatively concludes that the first-tier sodium level for meal and main dish products allows a "healthy" definition that is neither too strictly nor too broadly defined. The first-tier sodium level will allow consumers to meet current dietary guidelines for sodium intake while still maintaining flexibility in the diet. Additionally, the agency believes that by retaining the first-tier sodium level, a reasonable number of "healthy" meal and main dish products will remain available to consumers. Therefore, the agency has tentatively concluded that the current first-tier level of 600 mg sodium per serving size should be retained as the sodium criterion for "healthy" meal and main dish products. Accordingly, the agency is proposing to eliminate the second-tier sodium level of 480 mg for meal and main dish products and to make the first-tier sodium level permanent for those products.

#### *D. Conclusion*

FDA is proposing to permit the previously-established, second-tier sodium level to take effect for "healthy" individual foods and to retain the first-tier sodium level for "healthy" meal and main dish products. FDA believes that this combination of actions is necessary to provide for a reasonable number of "healthy" products in the marketplace. The marketplace data analysis indicated that the number of "healthy" individual foods has been increasing while the number of "healthy" meal and main dish products has been decreasing.



Further, the first-tier sodium level for “healthy” meal and main dish products provides a lower sodium intake than the amount that would be consumed if a meal or main dish product consisted of “healthy” individual foods at the second-tier sodium level. The agency believes that the proposed sodium requirements represent levels that are achievable by manufacturers but sufficiently restrictive to provide consumers with a meaningful definition of the term “healthy” that will assist them in constructing a diet consistent with dietary guidelines. Thus, FDA tentatively concludes that the second-tier sodium level is appropriate for individual foods, and the first-tier sodium level is appropriate for “healthy” meal and main dish products.

#### *E. Clarification*

To clarify the scope of implied nutrient content claims under § 101.65(d), FDA is modifying § 101.65(d)(1) to specify that a claim that suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, is an implied nutrient content claim if it is made in connection with either an explicit or implied claim or statement about a nutrient. This change makes the regulatory text consistent with the preamble discussions in both the proposed and final rules (58 FR 2944 at 2945, January 6, 1993; 59 FR 24232 at 24235, May 10, 1994), where FDA made clear that claims made in association with an implied claim or statement about a nutrient would be covered by the regulation. Thus, the regulation now states that a claim that suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, is an implied nutrient content claim if it is made in connection with an explicit or implicit claim or statement about a nutrient.

#### *F. Plain Language*

By January 1, 1999, Federal agencies were to use plain language in all proposed and final rulemaking documents published in the **Federal Register** (Ref. 10). FDA is therefore proposing to revise the format in § 101.65(d) for all nutrient requirements for the term “healthy.” The codified language is currently in a text-based format. FDA is proposing a summary table format. This new format should aid the reader in comprehending and following these regulations.

Finally, FDA is proposing several minor changes in the wording of § 101.65(d) to make the regulation more concise and easier to understand. These

changes are not intended to affect the meaning of the regulation.

#### **IV. Environmental Impact**

The agency tentatively concludes under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **V. Analysis of Economic Impacts**

##### *A. Preliminary Regulatory Impact Analysis*

FDA has examined the economic impacts of the proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, public safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). This proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million, adjusted for inflation. The current inflation-adjusted statutory threshold is \$115 million.

##### **1. The Need for Regulation**

To bear the term “healthy,” products must not exceed established levels for fat, saturated fat, cholesterol, and sodium. The existing regulation states that meals and main dishes, as defined in § 101.13(l) and (m) respectively, must have sodium levels no higher than 600

mg per serving size (usually the entire meal) in the first-tier compliance period, and sodium levels no higher than 480 mg per serving size in the second-tier compliance period, which was originally scheduled to begin on January 1, 1998. The regulation also states that “healthy” foods other than meals and main dishes must have sodium levels no higher than 480 mg per reference amount in the first-tier compliance period, and sodium levels no higher than the second-tier 360 mg per serving size thereafter. The agency initially stayed the second-tier sodium levels until January 1, 2000 (62 FR 15390, April 1, 1997). FDA has since extended the stay twice: First until January 1, 2003 (64 FR 12886), and more recently until January 1, 2006 (67 FR 30795, May 8, 2002).

In December 1996, ConAgra petitioned FDA to eliminate the second-tier, lower sodium levels. The petitioner claimed that these levels were too difficult to meet, and therefore would force the removal from the market of many products that were still healthy and contained less sodium than their direct competitors.

This proposal modifies the definition of the term “healthy” in only one respect: It makes the first-tier sodium level of 600 mg permanent for meals and main dishes. “Healthy” individual foods still would have to comply with the second-tier limit of 360 mg per serving once that limit goes into effect.

##### **2. Regulatory Options**

FDA identified several options in the ANPRM: (1) Make no change to the current rule, i.e. allow the second-tier sodium levels to go into effect; (2) amend the definition of “healthy” as requested in the petition, i.e. eliminate the second-tier sodium levels; (3) continue the stay to give producers time to develop technological alternatives to sodium; or (4) consider different second-tier sodium limits. Analyzing probable technological change (option 3) is beyond the scope of this analysis; innovation is very difficult to predict. FDA views any technological change as mitigating the eventual cost of this rule, but requests comments as to how to quantify this effect.

Also, analyzing alternative second-tier sodium limits in terms of net benefits (option 4) is not feasible in this analysis. The optimum sodium level for individual foods, meals, and main dishes balances the health benefits of limiting sodium intake with the cost to industry and of making food product preparation more complicated and the cost to consumers of limiting product choice. In the analysis that follows, we

argue that the first-tier sodium level strikes that balance better than the second-tier level for meals and main dishes, but that the second-tier level strikes the balance better for individual foods. Other sodium levels may perform well in this type of analysis, but FDA has no way of differentiating health effects or manufacturing costs due to marginal differences in the allowable sodium content of “healthy” food products.

Therefore, the options we consider for this analysis are option 1 (allow second-tier levels to take effect) and option 2 (eliminate second-tier levels), split into separate categories for individual foods (2a) and meals and main dishes (2b). The proposed rule would adopt 2b, but not 2a.

1. Implement the current rule without modification, which would make the second-tier sodium levels effective on January 1, 2006.

2a. Amend the current rule, adopting as permanent the first-tier sodium level for all or specific “healthy” individual foods.

2b. Amend the current rule, adopting as permanent the first-tier sodium level for “healthy” meals and main dishes.

2c. Amend the current rule, adopting as permanent the first-tier sodium levels for “healthy” meals and main dishes and for all or specific “healthy” individual foods.

The “baseline” in this case is the current rule or option 1, so the benefits of the other options are the reformulation, rebranding, and relabeling costs avoided by retaining the first-tier sodium content requirements for individual foods or meals and main dishes. The cost of the other options is the negative health impact due to a net increase in sodium intake under options 2a, 2b, and 2c.

**Option 2a: Retain the First-Tier Sodium Level for Individual “Healthy” Foods.** FDA considers the current rule’s second-tier sodium level for “healthy” appropriate for individual foods. Although this analysis does not quantify in detail the net benefit associated with lower sodium levels in food, the costs associated with option 2a in all likelihood outweigh the benefits. The agency does not have the information necessary to calculate the effects on the market of the 870 foods that use a “healthy” claim, but FDA invites comments regarding how to quantify the qualitative effects summarized here.

**Benefits of Option 2a.** The benefits are the reformulation, rebranding, and relabeling costs avoided by manufacturers if they do not have to modify their products to meet the

second-tier sodium level for individual foods. In the market analysis, FDA identified 870 individual food products among 69 brands that make a “healthy” claim (Ref. 2). The FLAPS survey also identified several additional individual foods that make a “healthy” claim but are not from a “healthy” brand (Ref. 4). However, according to the comments on the ANPRM and subsequent analysis by FDA, only 3 of the over 80 food product categories would have material trouble meeting the second-tier “healthy” sodium level: Soups, cheeses, and meats (primarily frankfurters and ham). Of the three food product categories that FDA tentatively concludes are impacted by this option, sodium levels for “healthy” meats are regulated by USDA and therefore are not part of this analysis. Discussions on cheese and soup categories follow.

Other individual foods in other categories may have costs associated with meeting the second-tier sodium level, but FDA has no information concerning costs for those other individual foods. FDA invites comments on the costs that may be incurred by other “healthy” individual foods, including dietary supplements, in meeting the second-tier sodium level.

**Cheese.** Reformulating cheeses to meet the second-tier sodium level would be difficult. However, FDA believes that, as of May 2001, every “healthy” cheese product had already been taken off the market. FDA identified 32 “healthy” cheeses, under one brand, on the market in 1999 according to the marketplace data analysis (Ref. 2). In an informal telephone inquiry, FDA confirmed that by May 2001, there were no longer “healthy” cheeses produced under this brand (Ref. 5).

Having no products to analyze prevents FDA from performing a detailed analysis of the potential impact of the second-tier sodium level on cheese. “Healthy” cheeses could have been taken off the market for several reasons. First, an aspect of the product unrelated to sodium content (e.g. lower fat requirements) could have been responsible for low product demand. If so, option 2a would not lead to any societal benefits through influencing the market for cheese. Second, firms may not be able to create an acceptable “healthy” cheese product even under the first-tier sodium level for individual foods. This means that there would be no cost or benefit difference between the first and second tiers of sodium content. Third, if “healthy” cheeses were taken off the market in anticipation of being unable to comply with the second-tier sodium level, adopting option 2a would

probably encourage producers to re-introduce “healthy” cheese products.

In this case, FDA believes it likely that sodium content was not the primary factor in the decision to take “healthy” cheeses off the market. Many light mozzarella cheeses currently have a sodium content lower than second-tier sodium levels—between 167 and 357 mg per 50 g serving in our examples from Washington, DC, area grocery stores (Ref. 5)—and the “healthy” version of this cheese was among the most popular sellers among all “healthy” cheeses but was still pulled from the market (Ref. 2).

**Soups.** Costs associated with the current rule, and therefore benefits of avoiding these costs under option 2a, would be small for soups. “Healthy” soups had about a 7 percent market share by sales in 1999, but a major producer of “healthy” soups supports the second-tier sodium level; this is persuasive evidence that the private benefits to producers of preserving “healthy” as a high-quality health signal can be as valuable as the private cost of reformulation. This producer states in its comments to the ANPRM that, for most major varieties of its brand of “healthy” soup, it was able to achieve taste parity under the second-tier sodium level. However, another major soup producer does not support the second-tier level.

**Costs of Option 2a.** The principal costs of this option are all associated with the deterioration of “healthy” as a signal of a truly healthy individual food.

Based on the comments to the ANPRM, over 90 percent of “healthy” individual foods could meet the second-tier sodium limit without material adverse changes in taste or texture. Cheeses and soups represent a small percentage of all “healthy” individual foods. Retaining the first-tier sodium level for all individual foods would diminish the effectiveness of the “healthy” low sodium signal substantially, compared to the current rule. Alternatively, if FDA retained the first-tier “healthy” sodium level only for soups and cheeses, FDA believes this inconsistency would also diminish the usefulness of the term “healthy” as a low sodium signal.

In addition, the current and proposed rule’s second-tier level for individual foods is more consistent with the “healthy” definition for meals and main dishes. As explained in detail in section III of this document, the first-tier sodium level for combinations of “healthy” individual foods allows significantly more sodium than when those same foods are combined into meals and main dishes. “Healthy” meal

and main dish products must contain at least two noncondiment food groups, and still can only contain 600 mg sodium per meal or main dish under the first-tier sodium level. In contrast, two “healthy” individual foods combined in exactly the same way could contain 720 mg sodium under the stayed second-tier level, and up to 960 mg sodium under option 2a, or 40 percent of the RDI. The current and proposed rule’s second-tier level for individual foods is fairly consistent with the meal and main dish first-tier sodium level, but the first-tier difference of up to 360 mg sodium between a meal and two individual foods is substantial and could have a health effect if consumers are using “healthy” specifically as a low sodium signal. FDA believes this inconsistency in the labeling claim “healthy” could lead to higher sodium intake, if the first-tier sodium level were to remain in effect for individual foods.

FDA believes that the major cost of option 2a is the increased health risk caused by higher sodium intake due to retaining the higher first-tier sodium level for individual foods. FDA further believes that the costs of this option outweigh the benefits of adopting as permanent the first-tier sodium limit for all or particular individual foods.

*Option 2b: Retain the First-Tier Sodium Level for Meals and Main Dishes (the Proposed Rule).*

*Costs of Option 2b.* The cost of this option, as in option 2a for individual foods, is the increased health risk due to higher sodium intake. However, FDA finds that adopting option 2b will not significantly affect the average amount of sodium consumed in an overall diet. The net increase in sodium intake under the proposed rule is insubstantial even under the most favorable assumptions of the effects of the current rule. Under some plausible scenarios, the average amount of sodium consumed could remain the same or actually increase if the current rule were implemented without amendment.

In the original analysis of the regulation defining the “healthy” claim, FDA referred to the many benefits of improved nutrition labeling, including decreased rates of cancer, coronary heart disease, obesity, hypertension, and allergic reactions to food. FDA also considered “healthy” claims an important contributor to the \$4.4 billion to \$26.5 billion benefit of improved food labels over the 20 years following the rule (59 FR 24232 at 24247 and 24248).

Several comments on the 1997 ANPRM expressed concern that “healthy” claims at the first-tier sodium level may undermine consumer attempts to improve their diets and health, as these meals are not truly healthy. An inaccurate “healthy” claim is not a useful signal that a product is indeed healthy.

In order to get a rough estimate of the difference in sodium intake between the current and proposed rule, we took a sample of 106 frozen meals and main dishes from a Washington, DC area grocery store (Ref. 5). The agency believes this sample is reasonably representative of the U.S. prepared dinner market, although it may not encompass all meal and main dish choices available nationwide. We also tested these results with a second Web-based sample (Ref. 5).

According to the Washington, DC grocery store sample, the current market for meals and main dishes can be characterized as having three segments. The first is the bargain segment, with two or three producers that offer basic meals, usually priced from \$1 to \$1.50 lower than the average product on the market. The second segment, or “normal” market, also has two or three major producers, with prices ranging from slightly lower to the same as the health-positioned goods in the third segment. Products in the second segment appear to compete mainly on taste or price rather than health attributes, although such products sometimes make health-related or dietary claims (e.g., “low-fat”). The third segment is the “claims” segment, which includes the “healthy” branded products, low-fat products, and more expensive specialty dishes such as organic goods. Many of these products prominently display fat and calorie information on the front of the package; these brands clearly use nutritional content as a marketing tool.

According to our analysis (Ref. 5), the “healthy” branded goods have the lowest average sodium content among the “claims” brands and the lowest average sodium content on the market. On average, they have 42 mg less sodium per meal than their next lowest competitor. Both the “healthy” branded goods and their main competitor that does not make “healthy” claims have average sodium levels under the first-tier limit of 600 mg for meals and main dishes.

We explore several possible consumer and producer responses to option 2b—retaining the first-tier sodium level for meals and main dishes—as compared to option 1—allowing the second-tier sodium level to go into effect—in the following scenarios. If FDA adopted option 1, firms would respond to the imposition of the second-tier sodium level for meals and main dishes in a strategic way. Among the “healthy” brands, producers would have the option of either reformulating their products to meet the second-tier level, or relabeling their products without the “healthy” claim or the “healthy” brand name. The concern here is the consumer response to these actions. Reformulated products may be less palatable or more expensive, leading to a loss of market share. Rebranded (or relabeled) products would no longer carry the “healthy” claim and therefore would not be subject to a sodium limit. Indeed, several independent comments to the ANPRM expressed concern that lowering the sodium requirement to the second-tier level could encourage a consumer to switch to higher sodium alternatives.

The scenarios are summarized in table 1 of this document. The first number in each cell is the average amount of sodium in mg and the second number in parentheses is the market share for each brand. The average sodium content amounts of 551 mg, 593 mg, 722 mg, and 856 mg per meal are the result of analysis explained in a technical memo (Ref. 5). The “healthy” brand has slightly over 9 percent of the total frozen dinner meal market when measured by sales volume, and the non-“healthy” brand 1 in the “claims” segment of the market has 10.5 percent. Nonfrozen meals and main dishes, including chili, are also important in the overall market, but 99 percent of the sales of the “healthy” brand and 100 percent of the sales of “claims” brand 2 are in the frozen meal category. The “other” brands in table 1 of this document represent the normal and bargain market segments previously described. We assume that the three “claims” brands in this analysis are a reasonable approximation to the “claims” market segment as previously described in this document. Each of their shares in the total market is divided by the sum of the shares of the three brands in the total market, which makes their market shares in the “claims” segment of the market (.45 + .52 + .03) equal to 1.

TABLE 1.—SODIUM CONSUMPTION SCENARIO ANALYSIS FOR SAMPLE 1 MEALS AND MAIN DISHES

Scenario	Healthy Brand Sodium mg (Market Share)	Claims Brand 1 Sodium mg (Market Share)	Claims Brand 2 Sodium mg (Market Share)	Other Sodium mg (Market Share)	Average Sodium mg
(1) Present market	551 (.45)	593 (.52)	722 (.03)	856 (0)	579
(2) Perfect reformulation (option 1)	476 (.45)	593 (.52)	722 (.03)	856 (0)	544
(3) Switch point, random share loss (option 1)	476 (.45 - .142)	593 (.52 + .047)	722 (.03 + .047)	856 (.047)	579
(4) Switch point, equal share loss to claims competitors (option 1)	476 (.45 - .193)	593 (.52 + .097)	722 (.03 + .097)	856 (0)	579
(5) Reformulation up (option 2b)	600 (.45)	593 (.52)	722 (.03)	856 (0)	600
(6a) Combined total response to option 1.	480 (.45 - .113)	593 (.52 + .056)	722 (.03 + .056)	856 (0)	566
(6b) Combined total response to option 2b.	580 (.45 + .04)	593 (.52 - .02)	722 (.03 - .02)	856 (0)	588
(6) Total effect (6b–6a)	—————	—————	—————	—————	22

Since option 1, or not amending the current rule, is the baseline for exploring the effect of option 2b, the first five scenarios are designed to demonstrate how different responses to the current rule (option 1) and the proposed rule (option 2b) affect the average amount of sodium consumed. Scenarios 6a and 6b combine the responses in the previous scenarios in an attempt to capture the total effect of the proposed rule. The last row, in the last column, is the total change in sodium when comparing the proposed rule (6b) to the option 1 (6a) (scenario 6—“total effect”).

*Scenario 1: The Present Market.* The first-tier sodium level applies until 2006, but firms may be trying to prepare for the second-tier sodium level, causing the average amount of sodium in the “healthy” brand to be lower than it would be under the proposed rule. The average “claims” segment meal, as reported in the last column of table 1 of this document, contains 579 mg sodium, the average “healthy” brand meal contains 551 mg sodium, and several “healthy” brand meals in this sample are under the second-tier sodium level of 480 mg sodium.

*Scenario 2: Perfect Reformulation.* Under the very optimistic perfect reformulation assumption, where the “healthy” manufacturer could replicate every aspect of its product except the sodium level, the sodium level of the average “claims” segment meal would decrease to 544 mg ( $476 \times .45 + 593 \times .52 + 722 \times .03$ ) under option 1. The difference between this and the current

market is 1.5 percent of the RDI of 2400 mg/day.

*Scenario 3: Random Loss of Market Share.* Some “healthy” brand consumers may switch to other products if manufacturers of “healthy” products cannot perfectly reformulate their products. In this scenario, the “healthy” brand loses market share to each of its competitors and to the rest of the market (“other” brands) in equal amounts. If the loss of market share is small, sodium levels will still decline under option 1. However, the average sodium level per meal and per main dish would not change if the “healthy” product lost 32 percent of its market (14 percent of the “claims” market) under these assumptions.

*Scenario 4: Loss of Market Share to Claims Competitors.* Consumers are likely to switch from “healthy” products to other “claims” products. Since these alternatives have less sodium than the rest of the frozen foods market, the amount of “healthy” business lost that would still leave average sodium levels lower or unchanged would be higher than in scenario 3 under option 1. If the “healthy” product lost 43 percent of its market share (which is smaller than the 45 percent of their products one major producer of “healthy” products stated the current rule would adversely affect) equally to both “claims” competitors, the average “claims” segment meal’s sodium content would be unchanged at 579 mg.

*Scenario 5: Reformulation Up to First-Tier Limit.* Here, we assume that only

the current belief that the second-tier restrictions will become effective discourages the “healthy” product from increasing the amount of sodium up to the first-tier limit. Therefore, under the proposed rule, every “healthy” meal and main dish would contain 600 mg of sodium per meal. These meals and main dishes would no longer be the low sodium products in the market, but they would still be the second lowest sodium products among major producers, with “claims” brand 1 slightly lower. The average meal and main dish in the “claims” market would increase to 600 mg as well, which is 21 mg per meal more than the current amount and 56 mg more than the total under scenario 2, the most optimistic, perfect reformulation total.

*Scenario 6: Total Effect.* Scenario 6, which is scenario 6a (combined total response to option 1) subtracted from scenario 6b (combined total response to option 2b), represents the agency’s estimate of the total effects of option 2b, which would adopt as permanent the first-tier sodium level for “healthy” meals and main dishes. In scenarios 6a and 6b, we make behavioral assumptions for both option 1 and option 2b.

*Scenario 6a: Combined Total Response to Option 1.* Of the “healthy” meals and main dishes in this sample, 75 percent are above and 25 percent are below the second-tier sodium level of 480 mg. If the second-tier sodium level were to take effect, we assume that the meals and main dishes already below 480 mg (25 percent of the total) would

be reformulated up to 480 mg. Based on comments to the ANPRM, we assume that 37.5 percent of all “healthy” meals and main dishes (one-half of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would be reformulated down to 480 mg of sodium without a loss of taste. An additional 19 percent of all healthy meals and main dishes (one-fourth of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would be reformulated even though the reformulation would lead to some loss of taste. The remaining 19 percent of all healthy meals and main dishes (one-fourth of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would either have “healthy” removed from the label or cease being produced.

The total response of producers to the second-tier level of 480 mg would therefore be:

- Producers increase the sodium level to 480 mg for the 25 percent of “healthy” meals and main dishes that are currently below 480 mg of sodium.
- Producers reduce the sodium level to 480 mg for 56 percent of “healthy” meals and main dishes (37.5 percent with no loss of taste, 19 percent with some loss of taste).
- Producers either drop “healthy” from the label or cease producing 19 percent of all “healthy” meals and main dishes.

In this scenario, consumers respond to the loss of taste and disappearance of products by switching choices within the “claims” segment of the market, which includes “healthy” and similar meals and main dishes. They switch with equal probability to any one of the three brands in the “claims” segment, which means that one-third will switch to another “healthy” product and two-thirds will switch to non-“healthy” products. The market share loss of the “healthy” brand is therefore 25 percent of its market, or two-thirds of the 37.5 percent of the market that experiences loss of taste, or disappearance of products. This is 11.3 percent of the total “claims” market. The average sodium intake implied by the market activity in this scenario under option 1 is 566 mg per meal.

**Scenario 6b: Combined Total Response to Option 2b.** We assume that producers will reformulate most, but not all, of the “healthy” products to the first-tier limit. We believe producers of “healthy” products will choose to position themselves as a slightly lower sodium alternative in this market, as they are currently positioned, but reformulate to increase sodium for taste reasons. Because of improved taste,

these producers increase their market share by 10 percent under this scenario, so the average sodium intake under the proposed amendment would be 588 mg per meal.

The difference between scenarios 6a and 6b is the best estimate of the “sodium cost” of the proposed rule, which is only 22 mg per meal.

FDA’s technical memo (Ref. 5) repeats the basic parts of this analysis for a second sample of products pulled from the Web sites of a producer of “healthy” products and a “claims” segment producer, which we performed as a stress test of the first sample conclusions. The result from this somewhat different sample of meal products is quite close to the 22 mg “sodium cost” calculated in scenario 6 of table 1 of this document.

According to our analysis, the sodium increase under option 2b, the proposed rule, would be insubstantial. Almost all studies linking sodium’s influence on hypertension, coronary heart disease, and stroke consider the effect of a change in sodium consumption two orders of magnitude larger than these changes. A 100 mmol (2,300 mg) difference per day is typical in both clinical and epidemiological studies; these studies do not address the relative dose-response relationship of the small sodium intake differences found in the scenarios. Even if the effect were linear (i.e., even if the health risk associated with the mg change per day in sodium due to this proposed rule were a simple percentage of the 2,300 mg risk), the total statistical lives saved by implementing the second-tier sodium level for meals and main dishes would be less than 1 under the total effects calculation in table 1 of this document and in the results of the second sample (Ref. 5). However, FDA does not make this linear assumption. FDA believes that the health effects from this low level of sodium increase are negligible.

**Benefits of Option 2b.** The benefits of avoiding reformulation and relabeling costs under this option are substantial. As discussed in section III. C of this document, FDA identified 148 meal and main dish products labeled “healthy” among 10 brands.

Producers would have to expend resources to reformulate their meals to meet the second-tier sodium level. Lost market share due to product reformulation would not be a net loss, but rather a transfer from one company to another. Reformulation costs themselves are the lower limit of the cost to society of the current rule. If producers could reformulate perfectly, without altering any property other than sodium content, then reformulation

would be the total cost of the rule. But if they could not replicate the desirable characteristics of their product, consumers would also suffer the utility loss of a market with fewer meal choices. This is a concern, since some dietitians recommend “healthy” claim products for their lower sodium content.

In the product samples used for the scenario analyses regarding the cost of the second-tier sodium level on meals and main dishes, a significant percentage (around 75 percent in the store-based sample and 50 percent in the Web site sample) of the major “healthy” producer’s products are above the second-tier sodium levels. If this is representative of the market as a whole, then approximately 74 to 111 products would need to reduce their sodium to meet the second-tier level. In estimating the total effects of the second-tier sodium level on meals and main dishes, we assumed 56 percent reformulation, or 83 of the 148 products on the market (see scenario 6a, in table 1 of this document).

Preliminary testing costs incurred in the first stage of reformulation—according to comments on the ANPRM received from a frozen meal “healthy” brand producer that has begun investigating possible reformulation—are well over \$1 million, but we do not have detailed reformulation cost estimates for meals and main dishes. The following reformulation cost estimations are based on a detailed example of tortilla chip reformulation, but the steps are typical of food reformulation in general. FDA requests information on any reformulation processes for the meal and main dish industry that are different from those described here.

The reformulation process typically starts in a laboratory, where researchers develop a new lower sodium formula for their meals. Then the company investigates availability and price of new ingredients (herbs, for example) and new equipment. If the reformulated meal passes these obstacles, it moves to the test kitchen, where researchers produce the product in small batches. If approved at this level, the meal graduates to a pilot plant. Cooking the product in large runs at the pilot plant may prove unsuccessful and require a manufacturer to restart the reformulation process, incurring additional expense. However, if pilot plant tests go well, full scale plant trials commence.

For reformulation of a meal, FDA assumes 5,000 hours of professional time at \$30 per hour, \$190,000 for development and pilot plant operating expenses, and \$100,000 for market

testing per product, based on this industry example. Since this reformulation would be undertaken to keep an existing product, we assume no relabeling or marketing costs. The total reformulation costs are therefore \$440,000 per product, or \$36,520,000 for the 83 meals assumed to be reformulated if adopting the second-tier sodium levels for meals and main dishes under scenario 6a. This cost would be incurred in the first year or two after the introduction of the rule. Assuming 50 percent of the cost is incurred per year for 2 years, and ignoring the time discount, the cost is \$18,260,000 per year.

Regardless of the relative costs of reformulation, FDA believes that a substantial number of market participants will choose to rebrand or relabel their products out of the "healthy" category if it becomes too restrictive. This has already happened under the current first-tier level: The number of "healthy" meals and main dish products dropped from 210 to 148 from 1993 through 1999, and the number of "healthy" brands dropped from 13 to 10. This time period spans the adoption of the current definition of "healthy" in 1994.

In this case, the direct costs of relabeling the product and conducting a marketing campaign would be social costs, since they represent extra investment that will not increase or improve the choice of products for consumers. Although FDA has no information about the costs of this type of rebranding activity to the manufacturer, they are most likely substantial.

However, the market may put a premium on "healthy" brands. This premium is a good measure of what consumers are willing to pay for the "healthy" signal. Since consumers would presumably be paying less for a less valuable product, the total effect of rebranding on consumer utility is negative but limited. However, firms have made an investment in the "healthy" brand based on an expected return closely related to this "willingness to pay" premium, and this investment would now be worthless if the product is unable to use the "healthy" claim. If the new definition of "healthy" with the second-tier sodium level is no more useful a health signal than the old definition, as we argue, this lost investment is a cost to society. In the original analysis of the regulation defining "healthy" (59 FR 24232 at 24247), which was issued in 1994, FDA estimated that the average premium (measured as the selling price difference) that the market placed on

"healthy" brand goods was \$0.57 per 16 oz equivalent. FDA used the Washington, DC store sample of 106 meals and main dishes referred to earlier to reestimate this premium for 2000, with similar results.

According to the analysis in FDA's technical memorandum (Ref. 5), the "healthy" brand competitor has a significant \$0.32 premium over the other major health positioned producer in this market, and at least as high a premium over the other major claims producer. Excluding the specialty organic products, the "healthy" brand is the highest priced product on the market in our sample. FDA believes \$0.32 to be a reasonable estimate of the market premium for the "healthy" brand. At average serving sizes of 10 oz, this translates into a \$0.51 premium per 16 oz, which is very close to the \$0.57 premium estimated in 1994.

In the 1994 analysis, the total value of each brand was based on this premium and average sales volumes. Sales of the brands still in the market were approximately 1.3 million units per product in 1999 (Ref. 2). Under the assumption of 19 percent rebranding in order for meals and main dishes to comply with the second-tier sodium level (scenario 6a), 28 products would be changed, with a total lost premium of \$11,648,000 per year (28 products x \$0.32 premium lost x average sales of 1.3 million units per year).

Adding this to the reformulation costs of the 83 products yields a total cost estimate of \$29,908,000 for years one and two, and a residual of the lost premium of \$11,648,000 for what would have been the rest of the normal life cycle of the lost "healthy" brand. Clearly, these costs are very large for a rule which would lead to little or no health benefit for the population, and avoiding these costs represents a large benefit of option 2b, the proposed rule.

*Option 2c: Retain the First-Tier Sodium Levels for "Healthy" Meals and Main Dishes and Individual "healthy" Foods.* The benefits and costs of option 2c are very close to the sum of the benefits and costs associated with options 2a and 2b. However, as stated in the discussion of option 2a previously in this document, retaining the first tier sodium levels for "healthy" individual foods would significantly decrease the consistency between sodium levels in "healthy" meals and main dishes and the sodium levels in meals put together by combining "healthy" individual foods. The less consistent the sodium levels in "healthy" meals and individual foods, the less consistent, and therefore less useful, is the low

sodium signal conveyed by the "healthy" label.

*Costs of Option 2c.* The cost of this proposed amendment, as with option 2a for individual foods, and option 2b for meals and main dishes, is the increased risk due to higher sodium intake and the diminishing effectiveness of the "healthy" low sodium signal. Since option 2c is essentially combining options 2a and 2b, the costs associated with a higher sodium intake are roughly the sum of the costs associated with options 2a and 2b.

As discussed previously in detail in this document, the average increased sodium intake occurring under option 2b is insubstantial (roughly 22 mg per meal) and the health effects from this low level of sodium increase are negligible. As stated previously, even under the conservative assumption of a linear dose response, the statistical lives saved by decreasing allowable sodium in "healthy" meals and main dishes to tier-2 levels would be less than 1. Furthermore, the effectiveness of the "healthy" low sodium signal would not be diminished since tier-1 levels of sodium for meals and main dishes allow for even less sodium than would appear in a meal composed of tier-2 individual "healthy" ingredients.

However, the potential increase in sodium intake, as discussed in detail under option 2a, due to relaxing the current level of sodium allowable in individual "healthy" foods, as well as the costs associated with the deterioration of the "healthy" signal, is significant.

Therefore, FDA believes the costs of option 2c, due to the reduced effectiveness of the "healthy" low sodium signal and the health risks due to increased sodium intake are significant, but only negligibly higher than those costs described for option 2a.

*Benefits of Option 2c.* The benefits of avoiding reformulation, rebranding, and relabeling costs under this option are roughly the sum of the benefits associated with options 2a and 2b.

FDA estimates, as discussed in the benefits section of option 2a, that the benefits of avoiding reformulation and relabeling costs associated by retaining the first-tier sodium levels for individual "healthy" foods are small.

As discussed in the benefits section of option 2b, the benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for "healthy" meals and main dishes are substantial. FDA estimates the total cost of reformulation and relabeling avoided in option 2b is \$29,908,000 for years one and two, and \$11,648,000 per year thereafter.

Therefore, FDA believes the benefits of option 2c, due to the avoided reformulation and relabeling costs associated with implementing the tier-2 sodium levels for both “healthy” meal and main dishes and “healthy” individual foods, are substantial but only slightly higher than those benefits described for option 2b.

*Net Benefits of Option 2c.* The net benefits of option 2c, retaining the first-tier level of sodium for both “healthy” meals and main dishes and individual “healthy” foods, are roughly the sum of the net benefits of options 2a and 2b.

The net benefits of option 2a, retaining the first-tier level of sodium for individual “healthy” foods are negative. The costs due to the health risk associated with increased sodium intake and the lost consistency and meaning of the “healthy” low sodium signal outweigh the benefits due to avoided reformulation, rebranding, and relabeling costs.

The net benefits of option 2b, retaining the first-tier level of sodium for “healthy” meals and main dishes are positive. The benefits in avoided reformulation, rebranding and relabeling costs substantially outweigh the negligible costs due to a very small potential increase in average daily sodium intake.

Since the net benefits of retaining the first-tier sodium level for “healthy” meals and main dishes are so substantial, FDA believes the net benefits of 2c, roughly the sum of the net benefits associated with 2a and 2b, are positive, but lower than the net benefits of the proposed rule, which would adopt as permanent the first-tier sodium limits for meals and main dishes only.

### 3. Net Benefits of the Proposed Rule

This analysis attempts to take limited data to illustrate in some detail what would actually take place in the market under the proposed rule. First, the costs to the “healthy” signal’s meaning and consistency outweigh the benefits of retaining the first-tier sodium level for individual foods. However, the meal and main dish analysis shows that while the benefits of retaining the first-tier sodium level (the costs foregone) are substantial for companies that would need to reformulate to comply with the second-tier sodium level or rebrand and relabel themselves out of the “healthy” market, the health costs associated with retaining the first-tier sodium level are both unquantifiable and most likely quite insubstantial or nonexistent. Therefore, the net benefits of the proposed rule, which would allow the second-tier sodium level to go into

effect for individual foods but would adopt as permanent the first-tier sodium level for meals and main dishes, are positive.

### B. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic effect of the rule on small entities. FDA finds that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would make permanent the less restrictive first-tier sodium level that meals and main dishes must meet to make a “healthy” claim. Without this proposed rule, the more restrictive second-tier sodium level would raise the costs of making a “healthy” claim on such products. If a small business were to market a “healthy” meal or main dish, it would be able to do so at lower cost under the proposed rule than if FDA left the current rule unmodified.

This proposed rule does not modify the current rule for the sodium content of “healthy” individual foods, under which the second-tier sodium level for those foods will take effect in 2006. Although the proposed rule does not impose a cost on small businesses over and above the rule that would otherwise be in place, FDA could lower the cost to small businesses of making a “healthy” claim by adopting as permanent the first-tier sodium level for individual foods.

As stated in the preliminary regulatory impact analysis discussed earlier, manufacturers of “healthy” foods in three categories—cheeses, soups, and some meats—are likely to be affected by the implementation of the second-tier sodium level. These foods are discussed in this document. As FDA has no information concerning costs for other individual foods and has received no comments indicating that manufacturers of these other foods would have difficulty meeting the second-tier sodium level, the agency tentatively concludes that the impact on small entities producing other types of “healthy” individual foods is not significant. FDA invites comments regarding small entities producing other “healthy” individual foods that may be adversely impacted by this proposed rule.

Of the affected individual food categories, meat is regulated by the

USDA and is not part of this analysis. The Small Business Administration (SBA) considers a cheese manufacturer small if it employs 500 or fewer workers, but no small or large business currently produces “healthy” cheese. The SBA considers a miscellaneous food manufacturer (neither SBA nor the Census Bureau specifically tracks soup producers) small if it employs 500 or fewer employees. According to the 1999 survey of foods used for this analysis, six companies produce “healthy” soups (Ref. 2), but none of these companies qualifies as a small business according to the standard SBA criteria. According to the 1999 Statistics for Businesses from the United States Census Bureau, over 90 percent of food manufacturers are small by the standard SBA criteria, so new entries into this industry in the future are likely to be small businesses. FDA tentatively concludes that this proposed rule will not have a significant impact on small entities.

### VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has tentatively determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Agriculture and Department of Health and Human Services, "Dietary Guidelines for Americans," 5th ed., U.S. Government Printing Office, Washington, DC, 2000.
2. Anderson, Ellen M., memorandum to file, September 3, 2002.
3. Kim, Heili, memorandum to file, July 16, 2001.
4. Anderson, Ellen M. and Heili Kim, memorandum to file, August 30, 2001.
5. Mancini, Dominic, memorandum to file, May 23, 2002.
6. *Cheese: Chemistry, Physics and Microbiology*, edited by P.F. Fox Chapman & Hall, 2d ed.
7. Kim, Heili, memorandum to file, May 15, 2001.
8. Anderson, Ellen M., memorandum to file, August 19, 2002.
9. Kim, Heili, memorandum to file, May 15, 2001.

10. National Partnership for Reinventing Government, Plain Language Action Network, Presidential Memorandum on Plain Language ([www.plainlanguage.gov/cites/memo.htm](http://www.plainlanguage.gov/cites/memo.htm)).

### List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

### PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. Section 101.65 is amended by revising paragraph (d) to read as follows:

### § 101.65 Implied nutrient content claims and related label statements.

\* \* \* \* \*

(d) *General nutritional claims.* (1) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and  
(ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat").

(2) You may use the term "healthy" or related terms (e.g., "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(C) An enriched cereal-grain product	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams (g) fat per RA <sup>1</sup> and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 milligrams (mg) cholesterol per RA and per 100 g	At least 10 percent of the RDI <sup>2</sup> or the DRV <sup>3</sup> per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber
(E) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	Low fat as defined in § 101.62(b)(3)	Low saturated fat as defined in § 101.62(c)	90 mg or less cholesterol per SS <sup>4</sup>	At least 10 percent of the RDI or the DRV per SS of two nutrients (for a main dish) or of three nutrients (for a meal) of the following six nutrients—vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this document	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)	The disclosure level for cholesterol specified in § 101.13(h) or less	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber

<sup>1</sup> RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).

<sup>2</sup> RDI means Reference Daily Intake (§ 101.9(c)(8)(iv)).

<sup>3</sup> DRV means Daily Reference Value (§ 101.9(c)(9)).

<sup>4</sup> SS means Serving Size Listed on the Label (§ 101.9(b)), also referred to as Labeled Serving Size.



(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be..
(A) A food with a RA <sup>1</sup> that is <i>greater</i> than 30 g or 2 tablespoons (tbsp)	360 mg or less sodium per RA and per SS <sup>2</sup>
(B) A food with a RA that is <i>equal to or less than</i> 30 g or 2 tbsp	360 mg or less sodium per 50 g <sup>3</sup>
(C) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	600 mg or less sodium per SS

<sup>1</sup> RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).

<sup>2</sup> SS means Serving Size Listed on the Label (§ 101.9(b)), also referred to as Labeled Serving Size.

<sup>3</sup> For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts per RA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the "prepared" form of the product.

(iii) The food complies with the definition and declaration requirements in part 101 of this chapter for any specific nutrient content claim used in labeling the food;

(iv) For foods in paragraph (d)(2)(i)(B) of this section, you may add ingredients that do not change the nutrient profile;

(v) Enriched cereal-grain products in paragraph (d)(2)(i)(C) of this section must conform to a standard of identity in part 136, 137, or 139 of this chapter; and

(vi) If you add a nutrient to the foods in paragraph (d)(2)(i)(D), (d)(2)(i)(E), or (d)(2)(i)(F) of this section to meet the 10 percent requirement, that addition must be consistent with the fortification policy for foods in § 104.20 of this chapter.

Dated: February 13, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-4100 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF DEFENSE

### National Security Agency/Central Security Services

#### 32 CFR Part 322

[NSA Reg. 10-35]

#### Privacy Act; Implementation

**AGENCY:** National Security Agency/Central Security Services, DOD.

**ACTION:** Proposed rule.

**SUMMARY:** The National Security Agency/Central Security Services (NSA/CSS) is proposing to revise its Privacy Act Program procedural and exemption rules.

Revisions to the procedural rule include updating the responsibilities assigned to NSA/CSS personnel, and establishing a queue to process Privacy Act requests. Requesters will no longer be required to wait a long period of time to learn that the Agency has a no records responsive to their requests or to obtain records that require minimal review.

The NSA/CSS exemption rules are being revised to add specific subsections of 5 U.S.C. 552a from which information may be exempt, and to add the reasons for taking the specific subsections.

**DATES:** Comments must be received on or before April 21, 2003 to be considered by this agency.

**ADDRESSES:** Send comments to the National Security Agency, Office of Policy, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755-6248.

**FOR FURTHER INFORMATION CONTACT:** Ms. Anne Hill at (301) 688-6527.

**SUPPLEMENTARY INFORMATION:** Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of \$100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities

because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

Section 202, Public Law 104-4, "Unfunded Mandates Reform Act". It has been determined that this Privacy Act rulemaking for the Department of Defense does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

Executive Order 13132, "Federalism". It has been determined that this Privacy Act rule for the Department of Defense does not have federalism implications. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

#### List of Subjects in 32 CFR Part 322

Privacy.

Accordingly, it is proposed that 32 CFR part 322 be revised to read as follows:

#### PART 322—NSA/CSS PRIVACY ACT PROGRAM

Sec.

- 322.1 Purpose and applicability.
- 322.2 Definitions.
- 322.3 Policy.
- 322.4 Responsibilities.
- 322.5 Procedures.
- 322.6 Establishing exemptions.
- 322.7 Exempt systems of records.

**Authority:** Pub. L. 93-579, 88 Stat. 1896 (5 U.S.C. 552a).

##### § 322.1 Purpose and applicability.

(a) This part implements the Privacy Act of 1974 (5 U.S.C. 552a), as amended and the Department of Defense Privacy Program (32 CFR part 310) within the National Security Agency/Central Security Service (NSA/CSS); establishes policy for the collection and disclosure of personal information about individuals; assigns responsibilities and establishes procedures for collecting personal information and responding to first party requests for access to records,

amendments of those records, or an accounting of disclosures.

(b) This part applies to all NSA/CSS elements, field activities and personnel and governs the release or denial of any information under the terms of the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

### § 322.2 Definitions.

(a) *Access*. The review of a record or a copy of a record or parts thereof in a system of records by an individual.

(b) *Confidential source*. A person or organization who has furnished information to the federal government under an express promise that the person's or the organization's identity will be held in confidence or under an implied promise of such confidentiality if this implied promise was made before September 27, 1975.

(c) *Disclosure*. The transfer of any personal information from a system of records by any means of communication (such as oral, written, electronic, mechanical, or actual review) to any person, private entity, or government agency, other than the subject of the record, the subject's designated agent or the subject's legal guardian.

(d) *Employees of NSA/CSS*. Individuals employed by, assigned or detailed to the NSA/CSS. This part also applies to NSA/CSS contractor personnel who administer NSA/CSS systems of records that are subject to the Privacy Act.

(e) *FOIA Request*. A written request for NSA/CSS records, made by any person, that either explicitly or implicitly invokes the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended. FOIA requests will be accepted by U.S. mail or its equivalent, facsimile, or the Internet, or employees of NSA/CSS may hand deliver them.

(f) *Individual*. A living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. The parent of a minor or the legal guardian of any individual also may act on behalf of an individual. Corporations, partnerships, sole proprietorships, professional groups, businesses, whether incorporated or unincorporated, and other commercial entities are not individuals.

(g) *Maintain*. Includes maintain, collect, use or disseminate.

(h) *Medical Records*. Documents relating to the physical care and treatment of an individual.

(i) *Privacy Act Request*. A written request containing a signature submitted by a U.S. citizen or alien admitted for permanent residence for access to or amendment of records on himself/herself which are contained in a PA

system of records. PA requests will be accepted via mail or facsimile, or NSA/CSS employees may hand deliver them. Digital signatures will be accepted via the Internet by October 21, 2003. Until then, PA requests will not be accepted via the Internet. Requests received via the Internet will not be acknowledged. Regardless of whether the requester cites the FOIA, PA, or no law, the request for records will be processed under both this part and the FOIA. Requests for amendments will be processed pursuant to the PA.

(j) *Personal information*. The collection of two or more pieces of information that is about an individual: e.g. name and date of birth, Social Security Number.

(k) *Personal notes*. Notations created in paper or electronic form for the convenience and at the discretion of the originator, for the originator's eyes only, and over which NSA/CSS exercises no control. Personal notes are not agency records within the meaning of the Privacy Act (PA) or the Freedom of Information Act (FOIA). However, once the personal note, or information contained therein, is shared with another individual, it becomes an Agency record and is subject to the provisions of the FOIA and, if appropriate, the PA.

(l) *Psychological Records*. Documents relating to the psychological care and treatment of an individual.

(m) *Record*. Any item, collection, or grouping of information, whatever the storage media (paper, electronic, etc.) about an individual or his or her education, financial transactions, medical history, criminal or employment history, and that contains his or her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint, voice print, or a photograph. The record must be in existence and under the control of NSA/CSS at the time a request is made.

(n) *Routine use*. The disclosure of a record outside NSA/CSS or the DoD for a use that is compatible with the purpose for which the information was collected and maintained by NSA/CSS. The routine use must be included in the published system of records.

(o) *System of Records*. A group of records under the control of a federal agency from which personal information is retrieved by the individual's name or by some identifying number, symbol, or other identifying particular assigned to an individual.

### § 322.3 Policy.

(a) The National Security Agency/Central Security Service shall maintain in its records only such information about an individual that is relevant and necessary to accomplish a purpose of the Agency, and that is required or authorized to be maintained by statute or Executive Order. Information about an individual shall, to the greatest extent practicable, be collected directly from the individual if the information may result in adverse determinations about the individual's rights, benefits, and privileges under any Federal program. Records used by this Agency in making adverse determinations about an individual shall be maintained with such accuracy, relevance, timeliness and completeness as is reasonably necessary to assure fairness to the individual. The Agency shall protect the privacy of individuals identified in its records, and shall permit an individual to request access to personal information in records on himself/herself and to request correction or amendment of factual information contained in such records. These policies are consistent with the spirit and intent of the PA, and are subject to exemptions under the Act, as defined in § 322.7, and legal requirements to protect sensitive NSA information such as the intelligence sources and methods the Agency employs to fulfill its mission.

(b) Pursuant to written requests submitted in accordance with the PA, the NSA/CSS shall make records available consistent with the Act and the need to protect government interests pursuant to subsections (d) and (k) of the Privacy Act. Oral requests for information shall not be accepted. Before the Agency responds to a request, the request must comply with the provisions of this part.

(c) In order that members of the public have timely access to unclassified information regarding NSA activities, requests for information that would not be withheld if requested under the FOIA or the PA may be honored through appropriate means without requiring the requester to invoke the FOIA or the PA. Although a record may require minimal redaction before its release, this fact alone shall not require the Agency to direct the requester to submit a formal FOIA or PA request for the record.

### § 322.4 Responsibilities.

(a) The Director's Chief of Staff (DC) is responsible for overseeing the administration of the PA. The Director of Policy (DC3), or the Deputy Director of Policy, if so designated, shall carry

out this responsibility on behalf of the Chief of Staff and shall:

(1) Provide policy guidance to NSA/CSS on PA issues.

(2) Provide policy guidance to PA coordinators for processing PA requests from NSA/CSS employees who will be using the records within NSA/CSS spaces.

(3) Provide training of NSA/CSS employees and contractors in the requirements of the PA. Specialized training is provided to special investigators and employees who deal with the news media or the public.

(4) Receive, process, and respond to PA requests from individuals and employees who require the information for use outside of NSA/CSS spaces.

(i) Conduct the appropriate search for and review of records.

(ii) Provide the requester with copies of all releasable material.

(iii) Notify the requester of any adverse determination, including his/her right to appeal an adverse determination to the NSA/CSS Appeal Authority.

(iv) Assure the timeliness of responses.

(5) Receive, process and respond to PA amendment requests to include:

(i) Obtain comments and supporting documentation from the organization originating the record.

(ii) Conduct a review of all documentation relevant to the request.

(iii) Advise the requester of the Agency's decision.

(iv) Notify the requester of any adverse determination, including his/her right to appeal the adverse determination to the NSA/CSS Appeal Authority.

(v) Direct the appropriate Agency organization to amend a record and advise other record holders to amend the record when a decision is made in favor of a requester.

(vi) Assure the timeliness of responses.

(6) Ensure that Agency employees (internal requesters) that have access to NSA/CSS spaces are given access to all or part of a PA record to which the employee was denied by the record holder when, after a review of the circumstances by the Director of Policy, it is determined that access should be granted. For those individuals who do not have access to NSA/CSS spaces see § 322.6 of this part.

(7) Conduct Agency reviews in accordance with OMB Circular A-130<sup>1</sup> and 32 CFR part 310.

(8) Deposit in the U.S. Treasury all fees collected as a result of charges

levied for the duplication of records provided under the PA and maintain the necessary accounting records for such fees.

(b) The NSA/CSS Privacy Act Appeal Authority is designated as the reviewing authority for requests for review of denials by the Director of Policy to provide access to a record and/or to amend a record. The PA Appeal Authority is the Deputy Director, NSA. In the absence of the Deputy Director, the Director's Chief of Staff serves as the Appeal Authority.

(c) The General Counsel (GC) or his designee shall:

(1) Advise on all legal matters concerning the PA.

(2) Advise the Director of Policy and other NSA/CSS organizations, as appropriate, of legal decisions including rulings by the Justice Department and actions by the DoD Privacy Board involving the PA.

(3) Review proposed responses to PA requests to ensure legal sufficiency, as appropriate.

(4) Provide a legal review of proposed Privacy Act notices and amendments for submission to the Defense Privacy Office.

(5) Assist, as required, in the preparation of PA reports for the Department of Defense and other authorities.

(6) Review proposals to collect PA information for legal sufficiency, assist in the development of PA statements and warning statements when required and approve prior to use.

(7) Represent the Agency in all judicial actions related to the PA by providing support to the Department of Justice and by keeping the DoD Office of General Counsel apprised of pending PA litigation. A litigation status sheet will be provided to the Defense Privacy Office.

(8) Assist in the education of new and current employees, including contractors, to the requirements of the PA.

(9) Review PA and PA Amendment appeals, prepare responses, and submit them to the NSA/CSS Appeal Authority for final decision.

(10) Notify the Director of Policy of the outcome of all appeals.

(d) The Associate Director for Human Resources Services or designee shall:

(1) Establish the physical security requirements for the protection of personal information and ensure that such requirements are maintained.

(2) Establish and ensure compliance with procedures governing the pledging of confidentiality to sources of information interviewed in connection with inquiries to determine suitability,

eligibility or qualifications for Federal employment, Federal contracts, or access to classified information.

(3) Retain copies of records processed pursuant to the PA. The retention schedule is six years from the date records were provided to the requester if deletions were made and two years if records were provided in their entirety.

(4) Ensure the prompt delivery of all PA requests to the Director of Policy.

(5) Ensure the prompt delivery of all Privacy Act appeals of an adverse determination to the NSA/CSS PA Appeal Authority staff.

(6) Ensure that forms used to collect PA information meet the requirements of the PA.

(7) Compile, when required, estimates of cost incurred in the preparation or modification of forms requiring PA Statements.

(8) Assist in the development of training courses to educate new and current Agency employees, including contractors, of the provisions of the PA.

(9) Respond to PA requests for access to records, as appropriate.

(10) Establish procedures for the protection of personal information and ensure compliance with the procedures.

(e) The Inspector General (IG) shall:

(1) Be alert to Privacy Act compliance and to managerial administrative, and operational problems associated with the implementation of this part and document any such problems and remedial actions, if any, in official reports to responsible Agency officials, when appropriate.

(2) Respond, as appropriate, to PA requests.

(3) Establish procedures for the protection of personal records under the control or in the possession of OIG and ensure compliance with the procedures.

(f) Chiefs of Directorates, Associate Directorates, and Field Elements shall:

(1) Ensure that no systems or subsets of Systems of Records other than those published in the **Federal Register** are maintained within their components or field elements.

(2) Establish rules of conduct for persons who design, use or maintain Systems of Records within their components or field elements and ensure compliance with these rules.

(3) Establish, in consultation with the Associate Director of Human Resources or designee, the physical security requirements for the protection of personal information and ensure that such requirements are maintained.

(4) Ensure that no records are maintained within their components or field elements which describe how any individual exercises rights guaranteed by the First Amendment to the

<sup>1</sup> Available from <http://www.whitehouse.gov/omb/circulars/index.html>.

Constitution of the United States unless expressly authorized by statute, or by the individual about whom the record is maintained, or unless pertinent to, and within the scope of, an authorized law enforcement activity.

(5) Ensure that records contained in the Systems of Records within their components or field elements are not disclosed to anyone other than in conformance with the Privacy Act, to include the routine uses for such records published in the **Federal Register**.

(6) Maintain only such information about an individual as is relevant and necessary to accomplish a purpose of the Agency required to be accomplished by statute and Executive Order.

(7) Maintain all records which are used by the Agency in making any determination about any individual with such accuracy, relevancy, timeliness, and completeness as is reasonably necessary to ensure fairness to the individual in any determination.

(8) Establish procedures for protecting the confidentiality of personal records maintained or processed by computer systems and ensure compliance with the procedures.

(9) Designate a primary and alternate PA coordinator to be responsible for PA matters and inform the Office of Policy of the designations. Subordinate PA coordinators may be appointed at office level.

(10) Ensure that the Privacy Act coordinators acquire the necessary training in the theory and administration of the Privacy Act.

(11) Ensure that the Privacy Act coordinators conduct, to the extent practicable, on-the-job PA training of supervisors and records handlers in their organizations.

(12) Respond to PA requests to review records, as appropriate.

(13) Establish procedures for the protection of personal records and ensure compliance with the procedures.

(14) Establish procedures to ensure that requests for copies of PA records needed for external use, outside of NSA/CSS, shall be delivered to the Director of Policy immediately upon receipt once the request is identified as a Privacy Act request or appears to be intended as such a request.

(15) Publish, as necessary, internal PA procedures which are consistent with the Privacy Act and this part.

(16) Maintain an accounting of disclosures of records as described in § 322.5 of this part.

(17) Coordinate with the Office of the General Counsel any proposed new record systems or changes (either alterations or amendments) to existing

systems. Notice of new record systems or alterations to existing systems must be published in the **Federal Register** at least 30 days and Congress and the Office of Management and Budget must be given 40 days to review the new/ altered system before implementation.

(18) Collect and forward to the Director of Policy information necessary to prepare reports, as requested.

(19) Respond promptly to the Director of Policy and the PA Appeal Authority decisions concerning the granting access to records, amending records, or filing statements of disagreements.

(20) Ensure that forms (paper or electronic) used to collect PA information meet the requirements of the PA.

(21) Establish procedures to ensure that requests to conduct computer matching are forwarded to the Director of Policy.

(g) Each field element shall designate a Privacy Act (PA) Coordinator to ensure compliance with this part and to receive and, where appropriate, process PA requests. Section 322.6 of this part describes the procedure for individuals to gain access to records and the responsibilities of the PA Coordinators. Consistent with the provisions of 32 CFR parts 285 and 286 and 32 CFR part 310 special procedures apply to the disclosure of certain medical records and psychological records. Field elements should consult the PA Coordinator of the Office of Occupational Health, Environment and Safety Services before disclosing such information. (See paragraph (d)(9) of this section.)

(h) All NSA/CSS organizations and field elements responsible for electronic/paper forms or other methods used to collect personal information from individuals shall determine, with General Counsel's concurrence, which of those forms or methods require Privacy Act Statements and shall prepare the required statements. The Office of Policy requires all organizations or elements using such forms or methods shall ensure that respondents read, understand, and sign the statements before supplying the requested information. In addition, organizations must obtain the Director of Policy and the Office of General Counsel approval prior to the collection of personal information in electronic format.

#### § 322.5 Procedures.

(a) The Director of Policy, or the Deputy Director of Policy, if so designated, shall provide guidance to Privacy Act Coordinators for processing requests and releasing NSA/CSS

information within the confines of the NSA/CSS. If any organization or element believes a request to review a PA record should be denied, it shall advise the requester of the procedures for requesting a review of the circumstances of the case by the Director of Policy.

(b) Persons Authorized Access to NSA/CSS Facilities:

(1) Requests from NSA/CSS affiliates with authorized access to NSA/CSS facilities to review and/or obtain a copy of PA records in a Systems of Records for use within NSA/CSS spaces or for the inspection of an accounting of disclosures of the record shall be in writing, using the Privacy Act Information Request form. Requests shall normally be submitted directly to the Privacy Act Coordinator in the office holding the record. In the case of requests for access to records maintained in the individual's own organization, the Privacy Act Coordinator for that organization shall direct the requester to the person or office holding the record. A Privacy Act Information Request form shall be submitted to the holder of each record desired. The Privacy Act Coordinator shall assist supervisors and record handlers in processing the request and shall maintain an accounting for reporting purposes. Individuals shall not be permitted to review or obtain an internal copy of IG, OGC and/or certain security records. The Personnel File, which was available upon request prior to the implementation of the Privacy Act, shall continue to be available for review without citing the Privacy Act or using the Privacy Act Information Request form.

(2) Requests to obtain a copy of PA records for use outside of NSA/CSS shall be forwarded to the Director of Policy, FOIA/PA Services (DC321) using the Privacy Act Information Request form or in any written format and must contain the individual's full name, signature, social security number, description of the records sought and a work or home phone number. Requests shall be processed pursuant to the Privacy Act and the FOIA.

(c) Persons Not Authorized Access to NSA/CSS Facilities:

(1) Requests from individuals who do not have authorized access to NSA/CSS facilities must be in writing, contain the individual's full name, current address, signature, social security number and a description of the records sought. The mailing address for the FOIA/PA office is: National Security Agency, ATTN: FOIA/PA Services (DC321), 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755-6248.

(2) FOIA/PA Services may, at its discretion, require an unsworn declaration or a notarized statement of identity. In accordance with 28 U.S.C. 1746, the language for an unsworn declaration is as follows:

(i) If executed without the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

(ii) If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

(d) General Provisions Regarding Access and Processing Procedures:

(1) The requester need not state a reason or otherwise justify the request. If the requester wishes to be accompanied by another person, the individual may be required to furnish a statement authorizing discussion or disclosure of the records in the presence of the other individual. If the requester wishes another person to obtain the records on his/her behalf, the requester shall provide a written statement appointing that person as his/her representative, authorizing that individual access to the records and affirming that such access shall not constitute an invasion of the requester's privacy or a violation of his/her rights under the Privacy Act. In addition, requests from parents or legal guardians for records on a minor may be accepted providing the individual is acting on behalf of the minor and evidence is provided to support his or her parentage (birth certificate showing requester as a parent) or guardianship (a court order establishing guardianship).

(2) The Director of Policy and FOIA/PA Services (DC321) shall endeavor to respond to a direct request to the NSA/CSS within 20 working days of receipt. In the event the FOIA/PA Services cannot respond within 20 working days due to unusual circumstances, the requester shall be advised of the reason for the delay and negotiate a completion date with the requester. Direct requests to NSA/CSS shall be processed in the order in which they are received. Requests referred to NSA/CSS by other government agencies shall be placed in the processing queue according to the date the requester's letter was received by the referring agency, if that date is known. If it is not known, it shall be placed in the appropriate processing queue according to the date of the requester's letter.

(3) FOIA/PA requests for copies of records shall be worked in

chronological order within six queues ("super easy," "sensitive/personal easy," "non-personal easy," "sensitive/personal voluminous," "non-personal complex," and "expedite"). The processing queues are defined as follows:

(i) Super Easy Queue—The super easy queue is for requests for which no responsive records are located or for material that requires minimal specialized review.

(ii) Sensitive/Personal Easy Queue—The sensitive/personal easy queue contains FOIA and PA records that contain sensitive personal information, typically relating to the requester or requester's relatives, and that do not require a lengthy review. DC321 staff members who specialize in handling sensitive personal information process these requests.

(iii) Non-Personal Easy Queue—The non-personal easy queue contains all other types of NSA records not relating to the requester, that often contain classified information that may require coordinated review among NSA components, and that do not require a lengthy review. DC321 staff members who specialize in complex classification issues process these requests.

(iv) Sensitive/Personal Voluminous Queue—The sensitive/personal voluminous queue contains FOIA and PA records that contain sensitive personal information, typically relating to the requester or requester's relatives, and that require a lengthy review because of the high volume of responsive records. These records may also contain classified information that may require coordinated review in several NSA components. DC321 staff members who specialize in handling sensitive personal information process these requests.

(v) Non-Personal Complex Queue—The non-personal complex queue contains FOIA records not relating to the requester that require a lengthy review because of the high volume and/or complexity of responsive records. These records contain classified, often technical information that requires coordinated review among many specialized NSA components, as well as consultation with other government agencies. DC321 staff members who specialize in complex classification issues process these requests.

(vi) Expedite Queue—Cases meeting the criteria for expeditious processing as defined in this section will be processed in turn within that queue by the appropriate processing team.

(4) Requesters shall be informed immediately if no responsive records are located. Following a search for and

retrieval of responsive material, the initial processing team shall determine which queue in which to place the material, based on the criteria above, and shall so advise the requester. If the material requires minimal specialized review (super easy), the initial processing team shall review, redact if required, and provide the non-exempt responsive material to the requester immediately. The appropriate specialized processing team on a first in, first out basis within its queue shall process all other material. These procedures are followed so that a requester will not be required to wait a long period of time to learn that the Agency has no records responsive to his request or to obtain records that require minimal review.

(5) Requests for expeditious processing must include justification and a statement certifying that the information is true and correct to the best of the requester's knowledge. Expedited processing shall be granted if the requester demonstrates a compelling need for the information. Compelling need is defined as the failure to obtain the records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual or there would be an imminent loss of substantial due process rights.

(6) A request for expedited handling shall be responded to within 10 calendar days of receipt. The requester shall be notified whether his/her request meets the criteria for expedited processing within that time frame. If a request for expedited processing has been granted, a substantive response shall be provided within 20 working days of the date of the expedited decision. If a substantive response cannot be provided within 20 working days, a response shall be provided as soon as practicable and the chief of FOIA/PA Services shall attempt to negotiate an acceptable completion date with the requester, taking into account the number of cases preceding it in the expedite queue and the volume or complexity of the responsive material.

(7) Upon receipt of a request, FOIA/PA Services (DC321) shall review the request and direct the appropriate PA coordinator to search for responsive records. If the search locates the requested records, the PA coordinator shall furnish copies of the responsive documents to the FOIA/PA office that in turn shall make a determination as to the releasability of the records. All releasable records, or portions thereof, shall be provided to the requester. However, if information is exempt pursuant to the FOIA and PA, the

requester shall be advised of the statutory basis for the denial of the information and the procedure for filing an appeal. In the instance where no responsive records are located, the requester shall be advised of the negative results and his/her right to appeal what could be considered an adverse determination. NSA does not have the authority to release another agency's information; therefore, information originated by another government agency shall be referred to the originating agency for its direct response to the requester or for review and return to NSA for response to the requester. The requester shall be advised that a referral has been made, except when notification would reveal exempt information.

(8) The requester shall not be charged a fee for the making of a comprehensible copy to satisfy the request for a copy of the documents. The requester may be charged for duplicate copies of the documents. However, if the direct cost of the duplicate copy is less than \$25.00, the fee shall be waived. Duplicating fees shall be assessed according to the following schedule: Office Copy \$.15 per page, Microfiche \$.25 per page, and Printed Material \$.02 per page. All payments shall be made by certified check or money order made payable to the Treasurer of the United States.

(9) A medical/psychological record shall normally be disclosed to the individual to whom it pertains. However, and consistent with 5 U.S.C. 552a(f)(3) of the Privacy Act, if in the judgment of an authorized Agency physician, the release of such information could have an adverse effect on the individual, the individual shall be advised that it is in his best interest to receive the records through a physician of the requester's choice or, in the case of psychological records, through a licensed Psychiatrist or licensed Clinical Psychologist of the requester's choice. NSA/CSS may require certification that the individual is licensed to practice the appropriate specialty. Although the requester shall pay any fees charged by the physician or psychologist, NSA/CSS encourages individuals to take advantage of receiving their records through this means. If, however, the individual wishes to waive receiving the records through this means, the records shall be sent directly to the individual.

(10) Recipients of requests from NSA/CSS employees and affiliates for access to records within the confines of the NSA/CSS campus shall acknowledge the request within 10 working days of receipt, and access should be provided

within 20 working days. If, for good cause, access cannot be provided within that time, the requester shall be advised in writing as to the reason and shall be given a date by which it is expected that access can be provided. If an office denies a request for access to a record, or any portion thereof, it shall notify the requester of its refusal and the reasons for it and shall advise the individual of the procedures for requesting a review of the circumstances by the Director of Policy. If the Director of Policy denies a request for access to a record or any portion thereof, the requester shall be notified of the refusal and the reasons the information was denied. The Director of Policy shall also advise the requester of the procedure for appealing to the NSA/CSS Privacy Act Appeal Authority. (See paragraph (e) of this section).

(11) Although classified portions of NSA/CSS records are exempt from disclosure pursuant to exemption (k)(1) of the Privacy Act and exemption (b)(1) of the FOIA, NSA, in its sole discretion, may choose to provide an NSA affiliate access to the classified portions of records about the affiliate if the affiliate possesses the requisite security clearance, special access approvals, and appropriate need-to-know for the classified information at issue. Classified records may only be accessed by fully cleared personnel in NSA/CSS spaces. Disclosure of classified records under this provision shall not operate as a waiver of PA exemption (k)(1), FOIA exemption (b)(1), or of any other exemption or privilege that would otherwise authorize the Agency to withhold the classified records from disclosure. NSA's determination regarding an affiliate's need-to-know is not subject to appeal under this or any other authority. All copies of classified records made available to an NSA affiliate under the procedures of this Part shall carry the following statement: "This classified material is provided to you under the provisions of the Privacy Act of 1974. Furnishing you this material does not relieve you of your obligations under the laws of the United States (See, e.g., section 798 of Title 18, U.S. Code) to protect classified information. You may retain this material under proper protection as specified in the NSA/CSS Classification Manual; you may not remove it from NSA/CSS facilities."

(12) The procedures described in this part do not entitle an individual to have access to any information compiled in reasonable anticipation of a civil action or proceeding, nor do they require that a record be created.

(13) Requesting or obtaining access to records under false pretenses is a violation of the Privacy Act and is subject to criminal penalties.

(e) Appeal of Denial of an Adverse Determination:

(1) Any individual advised of an adverse determination shall be notified of the right to appeal the initial decision within 60 calendar days of the date of the response letter and that the appeal must be addressed to the NSA/CSS FOIA/PA Appeal Authority, National Security Agency, 9800 Savage Road, Suite 6248, Fort George G. Meade, MD 20755-6248. The following actions are considered adverse determinations:

(i) Denial of records or portions of records.

(ii) Inability of NSA/CSS to locate responsive records.

(iii) Denial of a request for expeditious treatment.

(iv) Non-agreement regarding completion date of request.

(v) The appeal shall reference the initial denial of access and shall contain, in sufficient detail and particularity, the grounds upon which the requester believes the appeal should be granted.

(2) The GC or his/her designee shall process appeals and make a recommendation to the Appeal Authority:

(i) Upon receipt of an appeal regarding the denial of information or the inability of the Agency to locate records on an individual, the GC or his/her designee shall provide a legal review of the denial and/or the adequacy of the search for responsive material, and make other recommendations as appropriate.

(ii) If the Appeal Authority determines that additional information may be released, the information shall be made available to the requester within 20 working days from receipt of the appeal. The conditions for responding to an appeal for which expedited treatment is sought by the requester are the same as those for expedited treatment on the initial processing of a request.

(iii) If the Appeal Authority determines that the denial was proper, the requester must be advised 20 days after receipt of the appeal that the appeal is denied. The requester likewise shall be advised of the basis for the denial and the provisions for judicial review of the Agency's appellate determination.

(iv) If a new search for records is conducted and produces additional records, the additional material shall be forwarded to the Director of Policy, as the initial denial authority (IDA), for

review. Following review, the Director of Policy shall return the material to the GC with its recommendation for release or withholding. The GC will provide a legal review of the material, and the Appeal Authority shall make the release determination. Upon denial or release of additional information, the Appeal Authority shall advise the requester that more material was located and that the IDA and the Appeal Authority each conducted an independent review of the documents. In the case of denial, the requester shall be advised of the basis of the denial and the right to seek judicial review of the Agency's action.

(v) When a requester appeals the absence of a response to a request within the statutory time limits, the GC shall process the absence of a response as it would denial of access to records. The Appeal authority shall advise the requester of the right to seek judicial review.

(vi) Appeals shall be processed using the same multi-track system as initial requests. If an appeal cannot be responded to within 20 days, the requirement to obtain an extension from the requester is the same as with initial requests. The time to respond to an appeal, however, may be extended by the number of working days (not to exceed 10) that were not used as additional time for responding to the initial request. That is, if the initial request is processed within 20 days so that the extra 10 days of processing which an agency can negotiate with the requester are not used, the response to the appeal may be delayed for that 10 days (or any unused portion of the 10 days).

(f) Amendment of Records:

(1) Minor factual errors may be corrected without resort to the Privacy Act or the provisions of this part, provided the requester and record holder agree to that procedure. Whenever possible, a copy of the corrected record should be provided to the requester.

(2) Requests for substantive changes to include deletions, removal of records, and amendment of significant factual information, because the information is incorrect or incomplete, shall be processed under the Privacy Act and the provisions of this part. The PA amendment process is limited to correcting records that are not accurate (factually correct), relevant, timely or complete.

(3) The amendment process is not intended to replace other existing NSA/CSS Agency procedures such as those for registering grievances or appealing performance appraisal ratings. Also, since the amendment process is limited

to correcting factual information, it may not be used to challenge official judgments, such as performance ratings, promotion potential, and performance appraisals as well as subjective judgments made by supervisors, which reflect his/her observations and evaluations.

(4) Requests for amendments must be in writing, include the individual's name, signature, a copy of the record under dispute or sufficient identifying particulars to permit timely retrieval of the affected record, a description of the information under dispute and evidence to support the amendment request. The mailing address for the FOIA/PA office is National Security Agency, ATTN: FOIA/PA Services (DC321), 9800 Savage Road, Suite 6248, Fort George G. Meade, MD 20755-6248. Individuals who have access to NSA/CSS spaces may send their request through the internal mail system to DC321.

(5) FOIA/PA Services (DC321) shall acknowledge the amendment request within 10 working days of receipt and respond within 30 working days. The organization/individual who originated the information under dispute shall be given 10 working days to comment. On receipt of a response, FOIA/PA Services (DC321) shall review all documentation and determine if the amendment request shall be granted. If FOIA/PA Services (DC321) agrees with the request, it shall notify the requester and the office holding the record. The latter shall promptly amend the record and notify all holders and recipients of the records of the correction. If the amendment request is denied, the requester shall be advised of the reasons for the denial and the procedures for filing an appeal.

(g) Appeal of Refusals to Amend Records:

(1) If the Director of Policy, as the Initial Denial Authority, refuses to amend any part of a record it shall notify the requester of its refusal, the reasons for the denial and the procedures for requesting a review of the decision by the NSA/CSS Appeal Authority. The Appeal Authority shall render a final decision within 30 working days, except when circumstances necessitate an extension. If an extension is necessary, the requester shall be informed, in writing, of the reasons for the delay and of the approximate date on which the review is expected to be completed. If the NSA/CSS Appeal Authority determines that the record should be amended, the requester, FOIA/PA Services, and the office holding the record will be advised. The latter shall promptly amend the record and notify all recipients.

(2) If the NSA/CSS Privacy Act Appeal Authority denies any part of the request for amendment, the requester shall be advised of the reasons for denial, his or her right to file a concise statement of reasons for disputing the information contained in the record, and his or her right to seek judicial review of the Agency's refusal to amend the record. Statements of disagreement and related notifications and summaries of the Agency's reasons for refusing to amend the record shall be processed in the manner prescribed by 32 CFR part 310.

(h) Disclosures and Accounting of Disclosures

(1) No record contained in a System of Records maintained within the Department of Defense shall be disclosed by any means of communication to any person, or to any agency outside the Department of Defense, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record will be:

(i) To those officials and employees of the Agency who have a need for the record in the performance of their duties and the use is compatible with the purpose for which the record is maintained.

(ii) Required to be disclosed under the Freedom of Information Act, as amended.

(iii) For a routine use as described in NSA/CSS systems of records notices. The DoD "Blanket Routine Uses" may also apply to NSA/CSS systems of records. (See Appendix C to 32 CFR part 310).

(iv) To the Bureau of the Census for the purpose of planning or carrying out a census or survey or related activity authorized by law.

(v) To a recipient who has provided the Department of Defense or the Agency with advance, adequate written assurance that:

(A) The record will be used solely as a statistical research or reporting record;

(B) The record is to be transferred in a form that is not individually identifiable (*i.e.*, the identity of the individual cannot be determined by combining various statistical records); and

(C) The record will not be used to make any decisions about the rights, benefits, or entitlements of an individual.

(vi) To the National Archives and Records Administration as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the



Archivist of the United States or the designee of the Archivist to determine whether the record has such value. A record transferred to a Federal records center for safekeeping or storage does not fall within this category since Federal records center personnel act on behalf of the Department of Defense in this instance and the records remain under the control of the NSA/CSS. No disclosure accounting record of the transfer of records to Federal records center need be maintained.

(vii) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the NSA/CSS specifying the particular portion and the law enforcement activity for which the record is sought. Blanket requests for all records pertaining to an individual will not be accepted. A record may also be disclosed to a law enforcement agency at the initiative of the NSA/CSS when criminal conduct is suspected, provided that such disclosure has been established in advance as a "routine use."

(viii) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of the individual to whom the record pertains.

(ix) To Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, or any joint committee of Congress or subcommittee of any such joint committee. This does not authorize the disclosure of any record subject to this part to members of Congress acting in their individual capacities or on behalf of their constituents, unless the individual consents.

(x) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office.

(xi) Pursuant to an order of a court of competent jurisdiction.

(A) When a record is disclosed under compulsory legal process and when the issuance of that order or subpoena is made public by the court that issued it, efforts shall be made to notify the individual to whom the record pertains. This may be accomplished by notifying the individual by mail at his most recent address as contained in the Component's records.

(B) Upon being served with an order to disclose a record, the General Counsel shall endeavor to determine

whether the issuance of the order is a matter of public record and, if it is not, seek to be advised when it becomes public. An accounting of the disclosure shall be made at the time the NSA/CSS complies with the order or subpoena.

(xii) To a consumer reporting agency in accordance with section 3711(f) of Title 31.

(2) Except for disclosures made in accordance with paragraphs (h)(1)(i) and (ii) of this section, an accurate accounting of disclosures shall be kept by the record holder in consultation with the Privacy Act Coordinator.

(i) The accounting shall include the date, nature, and purpose of each disclosure of a record to any person or to another agency; and the name and address of the person or agency to whom the disclosure is made. There need not be a notation on a single document of every disclosure of a particular record, provided the record holder can construct from its System the required accounting information:

(A) When required by the individual;

(B) When necessary to inform previous recipients of any amended records, or

(C) When providing a cross reference to the justification or basis upon which the disclosure was made (including any written documentation as required in the case of the release of records for statistical or law enforcement purposes).

(ii) The accounting shall be retained for at least five years after the last disclosure, or for the life of the record, whichever is longer. No record of the disclosure of this accounting need be maintained.

(iii) Except for disclosures made under paragraph (h)(1)(vii) of this section, the accounting of disclosures shall be made available to the individual to whom the record pertains. The individual shall submit a Privacy Act Information Request form to the Privacy Act Coordinator in the office keeping the accounting of disclosures.

(3) Disclosures made under circumstances not delineated in paragraphs (h)(1)(i) through (xii) of this section shall only be made after written permission of the individual involved has been obtained. Written permission shall be recorded on or appended to the document transmitting the personal information to the other agency, in which case no separate accounting of the disclosure need be made. Written permission is required in each separate case; *i.e.*, once obtained, written permission for one case does not constitute blanket permission for other disclosures.

(4) An individual's name and address may not be sold or rented unless such

action is specifically authorized by law. This provision shall not be construed to require withholding of names and addresses otherwise permitted to be made public. Lists or compilations of names and home addresses, or single home addresses will not be disclosed, without the consent of the individual involved, to the public, including, but not limited to individual Congressmen, creditors, and commercial and financial institutions. Requests for home addresses may be referred to the last known address of the individual for reply at his discretion and the requester will be notified accordingly.

#### **§ 322.6 Establishing exemptions.**

(a) Neither general nor specific exemptions are established automatically for any system of records. The head of the DoD Component maintaining the system of records must make a determination whether the system is one for which an exemption properly may be claimed and then propose and establish an exemption rule for the system. No system of records within the Department of Defense shall be considered exempted until the head of the Component has approved the exemption and an exemption rule has been published as a final rule in the **Federal Register**.

(b) No system of records within NSA/CSS shall be considered exempt under subsection (j) or (k) of the Privacy Act until the exemption rule for the system of records has been published as a final rule in the **Federal Register**.

(c) An individual is not entitled to have access to any information compiled in reasonable anticipation of a civil action or proceeding (5 U.S.C. 552a(d)(5)).

(d) Proposals to exempt a system of records will be forwarded to the Defense Privacy Office, consistent with the requirements of 32 CFR part 310, for review and action.

(e) Consistent with the legislative purpose of the Privacy Act of 1974, NSA/CSS will grant access to nonexempt material in the records being maintained. Disclosure will be governed by NSA/CSS's Privacy Regulation, but will be limited to the extent that the identity of confidential sources will not be compromised; subjects of an investigation of an actual or potential criminal or civil violation will not be alerted to the investigation; the physical safety of witnesses, informants and law enforcement personnel will not be endangered, the privacy of third parties will not be violated; and that the disclosure would not otherwise impede effective law enforcement. Whenever possible, information of the above



nature will be deleted from the requested documents and the balance made available. The controlling principle behind this limited access is to allow disclosures except those indicated above. The decisions to release information from these systems will be made on a case-by-case basis.

(f) Do not use an exemption to deny an individual access to any record to which he or she would have access under the Freedom of Information Act (5 U.S.C. 552).

(g) Disclosure of records pertaining to personnel, or the functions and activities of the National Security Agency shall be prohibited to the extent authorized by Pub. L. 86-36 (1959) and 10 U.S.C. 424.

(h) Exemptions NSA/CSS may claim.

(1) General exemption. The general exemption established by 5 U.S.C. 552a(j)(2) may be claimed to protect investigative records created and maintained by law enforcement activities of the NSA.

(2) Specific exemptions. The specific exemptions permit certain categories of records to be exempt from certain specific provisions of the Privacy Act.

(i) (k)(1) exemption. Information properly classified under Executive Order 12958 and that is required by Executive Order to be kept secret in the interest of national defense or foreign policy.

(ii) (k)(2) exemption. Investigatory information compiled for law-enforcement purposes by non-law enforcement activities and which is not within the scope of Sec. 310.51(a). If an individual is denied any right, privilege or benefit that he or she is otherwise entitled by federal law or for which he or she would otherwise be eligible as a result of the maintenance of the information, the individual will be provided access to the information except to the extent that disclosure would reveal the identity of a confidential source. This subsection when claimed allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(iii) (k)(3) exemption. Records maintained in connection with providing protective services to the President and other individuals identified under 18 U.S.C. 3506.

(iv) (k)(4) exemption. Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8.

(v) (k)(5) exemption. Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information, but only to the extent such material would reveal the identity of a confidential source. This provision allows protection of confidential sources used in background investigations, employment inquiries, and similar inquiries that are for personnel screening to determine suitability, eligibility, or qualifications.

(vi) (k)(6) exemption. Testing or examination material used solely to determine individual qualifications for appointment or promotion in the federal or military service, if the disclosure would compromise the objectivity or fairness of the test or examination process.

(vii) (k)(7) exemption. Evaluation material used to determine potential for promotion in the Military Services, but only to the extent that the disclosure of such material would reveal the identity of a confidential source.

#### **§ 322.7 Exempt systems of records.**

(a) All systems of records maintained by the NSA/CSS and its components shall be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1) to the extent that the system contains any information properly classified under Executive Order 12958 and that is required by Executive Order to be kept secret in the interest of national defense or foreign policy. This exemption is applicable to parts of all systems of records including those not otherwise specifically designated for exemptions herein, which contain isolated items of properly classified information.

(b) GNSA 01:

(1) *System name:* Access, Authority and Release of Information File.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of

an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(c) GNSA 02:

(1) *System name:* Applicants.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to

5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA

will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(d) GNSA 03:

(1) *System name:* Correspondence, Cases, Complaints, Visitors, Requests.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(iii) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(iv) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2), (k)(4), and (k)(5) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(2), (k)(4), and (k)(5)

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede

case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(e) GNSA 04:

(1) *System name:* Military Reserve Personnel Data Base.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them

with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(f) GNSA 05:

(1) *System name:* Equal Employment Opportunity Data.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled

by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(iii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2) and (k)(4) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(2) and (k)(4).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(g) GNSA 06:

(1) *System name:* Health, Medical and Safety Files.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service may be exempt pursuant to 5 U.S.C. 552a(k)(6), if the disclosure would compromise the objectivity or fairness of the test or examination process.

(iii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) and (k)(6) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5) and (k)(6).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights

normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(h) GNSA 08:

(1) *System name:* Payroll and Claims.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2) may be exempt from

the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(2).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(i) GNSA 09:

(1) *System name:* Personnel File.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service may be exempt pursuant to 5 U.S.C. 552a(k)(6), if the disclosure would compromise the objectivity or fairness of the test or examination process.

(iii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) and (k)(6) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5) and (k)(6).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(j) GNSA 10:

(1) *System name:* Personnel Security File.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(iii) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service may be exempt pursuant to 5 U.S.C. 552a(k)(6), if the disclosure would compromise the objectivity or fairness of the test or examination process.

(iv) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2), (k)(5), and (k)(6) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(2), (k)(5), and (k)(6).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(k) GNSA 12:

(1) *System name:* Training.

(2) *Exemption:* (i) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian

employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(ii) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service may be exempt pursuant to 5 U.S.C. 552a(k)(6), if the disclosure would compromise the objectivity or fairness of the test or examination process.

(iii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(5) and (k)(6) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(5), and (k)(6).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and

access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(l) GNSA 13:

(1) *System name*: Archival Records.

(2) *Exemption*: (i) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(4) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority*: 5 U.S.C. 552a(k)(4).

(4) *Reasons*: (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of

information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(m) GNSA 14:

(1) *System name*: Library Patron File Control System.

(2) *Exemption*: (i) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(4) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority*: 5 U.S.C. 552a(k)(4).

(4) *Reasons*: (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence;

enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(n) GNSA 15:

(1) *System name*: Computer Users Control System.

(2) *Exemption*: (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority*: 5 U.S.C. 552a(k)(2).

(4) *Reasons*: (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are

under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(o) GNSA 17:

(1) *System name:* Employee Assistance Service (EAS) Case Record System.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is

denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(iii) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(iv) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2), (k)(4), and (k)(5) may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority:* 5 U.S.C. 552a(k)(2), (k)(4), and (k)(5).

(4) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation.

Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting

of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

(p) GNSA 18:

(1) *System name:* Operations Files.

(2) *Exemption:* (i) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(ii) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(iii) All portions of this system of records which fall within the scope of 5 U.S.C. 552a(k)(2) and (k)(5) may be exempt from the provisions of 5 U.S.C.



552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f).

(3) *Authority*: 5 U.S.C. 552a(k)(2) and (k)(5).

(4) *Reasons*: (i) From subsection (c)(3) because the release of the disclosure accounting would place the subject of an investigation on notice that they are under investigation and provide them with significant information concerning the nature of the investigation, thus resulting in a serious impediment to law enforcement investigations.

(ii) From subsections (d) and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable

information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because there is no necessity for such publication since the system of records will be exempt from the underlying

duties to provide notification about and access to information in the system and to make amendments to and corrections of the information in the system.

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NSA will, nevertheless, continue to publish such a notice in broad generic terms, as is its current practice.

Dated: February 6, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4063 Filed 2-19-03; 8:45 am]

**BILLING CODE 5001-08-U**



# Notices

Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Commission on the Application of Payment Limitations for Agriculture

#### Payment Limitations

**AGENCY:** Farm Service Agency and Commodity Credit Corporation, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Commission on the Application of Payment Limitations for Agriculture (Commission) was mandated by section 1605 of the Farm Security and Rural Investment Act of 2002 (the 2002 Act), Public Law 107-171. The Farm Service Agency (FSA) provides administrative and financial support for the Commission, using Commodity Credit Corporation (CCC) funds. The Commission will study the effects of further limitations on the receipt of direct payments, counter-cyclical payments, loan deficiency payments and marketing loan gains by individuals and other entities. The study is to be transmitted to the President, the Committee on Agriculture, Nutrition and Forestry of the Senate, and the Committee on Agriculture of the House of Representatives. The Commission is also authorized to make recommendations it deems appropriate, which may include the feasibility of improving the application and effectiveness of payment limitations.

The Commission held its first meeting on January 23 and 24, 2003, in Washington, D.C. The Commission concluded that public input would be helpful in conducting its assessments of payment limitations. This notice provides the public the opportunity to comment on key issues that the Commission expects to address in its study.

**DATES:** Comments must be received in writing by March 24, 2003.

**ADDRESSES:** Send comments in writing, by mail, to Payment Limit Commission Comments, USDA/FSA/EPAS, Stop 0508, 1400 Independence Ave., SW, Washington, DC 20250-0508, or by email to

[payment.limit.comm@wdc.usda.gov](mailto:payment.limit.comm@wdc.usda.gov). This notice may also be accessed via the Internet through the FSA homepage, at <http://www.fsa.usda.gov>. All comments, including names and addresses when provided, are placed in the record and are available for public inspection.

**FOR FURTHER INFORMATION CONTACT:** John Jenkins, USDA/FSA/EPAS, Stop 0508, 1400 Independence Ave., SW., Washington, DC 20250-0508; telephone: (202) 720-2100; fax: (202) 690-2186; submit e-mail to: [John.Jenkins@usda.gov](mailto:John.Jenkins@usda.gov). Subject: Payment Limits.

#### SUPPLEMENTARY INFORMATION:

##### *General Information about the Commission*

The 2002 Act directed that the Commission consist of three members appointed by the Secretary of Agriculture; three members appointed by the Committee on Agriculture, Nutrition, and Forestry of the Senate; three members appointed by the Committee on Agriculture of the House of Representatives; and the USDA Chief Economist. The Secretary of Agriculture designated the USDA Chief Economist to serve as Commission Chairperson. The 2002 Act directs the Commission to conduct a study on the effects of further payment limitations on the receipt of direct payments, counter-cyclical payments and marketing loan gains and loan deficiency payments. The study is to be transmitted to the President, the Committee on Agriculture, Nutrition and Forestry of the Senate, and the Committee on Agriculture of the House of Representatives. The Commission is also authorized to make recommendations it deems appropriate. The Commission is to report the results of its study by May 13, 2003.

The Joint Explanatory Statement of the Committee of Conference for the 2002 Act indicates that the Managers of the Conference intended for the Commission to examine the feasibility of improving the application and effectiveness of payment limitations, including the use of commodity certificates and the unlimited forfeiture of loan collateral. The 2002 Act also

provides the Commission the authority to hold hearings, take testimony and receive evidence it considers necessary to conduct the study.

At its initial meeting in January 2003, the Commission concluded that public hearings are not feasible given the time available to complete its study. However, the Commission concluded that public comments on the payment limitation issues to be addressed by the Commission would be helpful. Consequently, the Commission decided to seek written comments from the public.

#### *Key Issues for Comment*

The Commission is specifically interested in receiving public input on the following:

1. The impacts of further payment limitations on the receipt of direct payments, counter-cyclical payments, marketing loan gains and loan deficiency payments on:

- (a) Farm income;
- (b) Land values;
- (c) Rural communities;
- (d) Agribusiness infrastructure;
- (e) Planting decisions of producers affected; and
- (f) Prices of all agricultural commodities, including fruits and vegetables and other specialty crops.

Comments are encouraged on the impact of farm program payments on the above and on the effects of further limitations on these issues. The range of effects is likely to depend on what further limitations are being evaluated. The phrase "further limitations" is not defined in the 2002 Act. The Commission believes that further limitations would be limitations that would result in total payments to producers being less than the level that would prevail under the payment limitations of the 2002 Act. Further limitations could be achieved a number of ways including: (1) Reducing the current dollar limitations imposed on specific types of payments, such as direct payments, that can be received by a producer, (2) restricting the number or types of entities eligible for payments, or (3) restricting or precluding payments based on a variety of other criteria, such as income. Each of these approaches may have different effects on producers and the agricultural economy, even if the total dollar reduction in payments is equal. The Commission welcomes comments on the effects of payments

and further payment limitations under alternative approaches. The Commission requests that commentors identify the approaches they are assessing along with analytical methods and data employed to reach their conclusions.

2. The feasibility of improving the application and effectiveness of payment limitations, including the use of commodity certificates and the unlimited forfeiture of loan collateral. Payment limits currently involve complex determinations by the Farm Service Agency on the eligibility of persons for payments. Compliance with payment limitation provisions may involve extensive documentation of business organization and other information. It appears that the payment limit program results in a range of costs on producers and the government. The Commission seeks comments on the feasibility of improving the administration of payment limitations and reducing these costs. Questions have also been raised regarding the effectiveness of payment limitations. One measure of effectiveness is the degree to which payment limitations reduce payments that otherwise would be made. Some estimates suggest the amount of payments not made to producers participating in farm programs as a result of payment limitations is relatively small compared with the level of payments that are made. Other measures of effectiveness may be appropriate to assess, including possible impacts on the structure and size of farms. The Commission seeks comments on the effectiveness of payment limitations and the feasibility of making payment limits more effective in cost-efficient ways.

3. The expected response of farmers and ranchers if payment limitations become more stringent. For example, would affected producers increase or reduce farm size? Would producers shift production to alternative commodities? Would producers change the legal organization of their businesses? Some commentors may be able to poll producers on how they might react to alternative approaches to tightening payment limitations. If so, the Commission requests information on the types and locations of farms surveyed.

4. Any other information relevant to the study objectives of the Commission.

#### *Regulatory Findings*

This notice is being issued to obtain public comment regarding issues associated with the study of the Commission on the Application of Payment Limitations for Agriculture.

There are no regulatory findings associated with this notice.

Signed in Washington, DC, on February 13, 2003.

**Keith Collins,**

*Chairman, Commission on the Application of Payment Limitations for Agriculture.*

[FR Doc. 03-4082 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-05-U**

## **DEPARTMENT OF AGRICULTURE**

### **Agricultural Marketing Service**

**[Doc. No. FV-03-328]**

#### **United States Standards for Grades of Frozen Celery**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is soliciting comments on its proposal to create new United States Standards for Grades of Frozen Celery. USDA received a petition from a grower and a processor of celery to create grade standards for frozen celery that will include a description of the product, style, sample unit size, grades, ascertaining the grade by sample, and ascertaining the grade by lot. The proposed standard is intended to provide a common language for trade, and a means of measuring value in the marketing of frozen celery.

**DATES:** Comments may be submitted on or before April 21, 2003.

**ADDRESSES:** Written comments may be submitted to: Karen L. Kaufman, Processed Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, STOP 0247, 1400 Independence Avenue SW., Washington, D.C. 20250-0247; fax (202) 690-1087; or e-mail [karen.kaufman@usda.gov](mailto:karen.kaufman@usda.gov).

Comments should reference the date and page of this issue of the **Federal Register**. All comments received will be made available for public inspection at the address listed above during regular business hours and on the Internet.

The draft of the United States Standards for Grades of Frozen Celery are available either through the address cited above or by accessing AMS's Home Page on the Internet at: <http://www.ams.usda.gov/fv/ppbdocketlist.htm>. Any comments received regarding this proposed standard will also be posted on that site.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Kaufman at (202) 720-5021 or e-mail at [karen.kaufman@usda.gov](mailto:karen.kaufman@usda.gov).

**SUPPLEMENTARY INFORMATION:** Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621-1627), as amended, directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices \* \* \*." AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables are maintained by USDA/AMS/Fruit and Vegetable Programs and may be obtained by writing to the above address or on the internet at <http://www.ams.usda.gov/standards/standpfv.htm>.

AMS is proposing to establish the U.S. Standards for Grades of Frozen Celery using the procedures that appear in Part 36 of Title 7 of the Code of Federal Regulations (7 CFR Part 36).

#### **Proposed by the Petitioner**

The petitioner, a grower and a processor of celery, requested that USDA develop a standard for frozen celery to be used by the industry. The petitioner provided information on style, sample size and description to AMS to develop the standard. AMS visited the petitioner's facility to collect information on grades of frozen celery and how to ascertain the grade of a sample and of a lot.

AMS prepared a discussion draft of the frozen celery standard, and distributed copies for input to the petitioner, the American Frozen Food Institute (AFFI), and the National Food Processors Association (NFPA). Input from the above groups was used to develop the proposed standard.

#### **Proposed by Fruit and Vegetable Programs, AMS**

A notice proposing to create new United States Standards for Grades of Frozen Celery based on the petition was published in the May 2, 2001, **Federal Register** (66 FR 21908). AMS received four comments in response to the notice. All of the responses but one were generally in favor of the new standard. These comments are available by accessing AMS's Home Page on the Internet at: <http://www.ams.usda.gov/fv/ppb.html>.

One commentor did not see the need for a standard for frozen celery and felt

the standard was too subjective. The other commentators were in favor of a standard for frozen celery and proposed changes to the Table I-Allowances For Defects In Frozen Celery for grade "A" and "B," "sliced" and "diced" styles. These changes included a reduction in the sample size for Table I from a maximum-per 500 grams to maximum-per 283 grams for a 10-ounce portion, a separate allowance for seriously blemished units from blemished units, decrease the number of leaf material larger than a 1/4" from "20 pieces" to "10 pieces," change mechanical damage from "no more than 3 pieces" to "no more than 3% by weight" and for insect damaged change from "none" to "0.5%."

Based on these comments, AMS has revised the proposed standard for grades of frozen celery. AMS is proposing to establish the U.S. Standards for Grades of Frozen Celery following the standard format for U.S. Grade Standards. AMS is proposing to define "frozen celery" and establish "sliced" and "diced" as the style designations. The proposal will also define the quality factors that affect frozen celery and determine sample unit sizes for this commodity.

This proposal will establish the grade levels "A," "B" and "Substandard" and assign the corresponding score points for each level. The proposed tolerance for each quality factor as defined for each grade level will be established.

The grade of a sample unit of frozen celery will be ascertained by considering the factors of varietal characteristics flavor and odor, which are not scored; the ratings for the factors of color, defects, and character, which are scored; the total score; and the limiting rules which apply. This proposal will provide a common language for trade, a means of measuring value in the marketing of frozen celery, and provide guidance in the effective utilization of frozen celery. The official grade of a lot of frozen celery covered by these standards will be determined by the procedures set forth in the Regulations Governing Inspection and Certification of Processed Products Thereof, and Certain Other Processed Food Products (§ 52.1 to 52.83).

This notice provides for a 60 day comment period for interested parties to comment on changes to the standards.

**Authority:** 7 U.S.C. 1621-1627.

Dated: February 13, 2003.

**A.J. Yates,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 03-4081 Filed 2-19-03; 8:45 am]

**BILLING CODE 3410-02-U**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Siskiyou County Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Siskiyou County Resource Advisory Committee will meet in Yreka, California, February 24, 2003. The meeting will include routine business including outreach to the public, conflict of interest, and a presentation on USFS Fire Fuels Management activities.

**DATES:** The meeting will be held February 24, 2003 from 4 p.m. until 6:30 p.m.

**ADDRESSES:** The meeting will be held at the Yreka High School Library, Preece Way, Yreka, California.

**FOR FURTHER INFORMATION CONTACT:** Don Hall, RAC Coordinator, Klamath National Forest, (530) 841-4468 or electronically at [donaldhall@fs.fed.us](mailto:donaldhall@fs.fed.us).

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public. Public comment opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: February 11, 2003.

**Margaret J. Boland,**

*Designated Federal Official.*

[FR Doc. 03-4025 Filed 2-19-03; 8:45 am]

**BILLING CODE 3410-11-M**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Determining Fees for Recreation Residences Permits During the Transition Period of the Cabin User Fee Fairness Act of 2000

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of issuance of interim directive.

**SUMMARY:** The Forest Service is issuing an interim directive to provide direction to Forest Service employees for assessing fees for recreation residence special use permits pursuant to the Cabin User Fee Fairness Act of 2000. The direction in this interim directive applies during the transition period as provided by section 614 of the act until the agency adopts final rules, directives, and appraisal guidelines. This interim directive is issued as ID 2709.11-2003-1 to Forest Service Handbook 2709.11, chapter 30.

**DATES:** This interim directive is effective February 20, 2003.

**ADDRESSES:** This interim directive (ID 2709.11-2003-1) is available electronically from the Forest Service via the World Wide Web/Internet at <http://www.fs.fed.us/im/directives>. Single paper copies of the interim directive also are available by contacting Randy Karstaedt, Forest Service, USDA, Lands Staff (Mail Stop 1124), 1400 Independence Avenue, SW., Washington, DC 20250-1124 (telephone 202-205-1256).

**FOR FURTHER INFORMATION CONTACT:** Randy Karstaedt, Lands Staff (202-205-1256), Forest Service, USDA.

**SUPPLEMENTARY INFORMATION:** The Forest Service is currently developing proposed regulations, directives, and appraisal guidelines in response to the requirements of the Cabin User Fee Fairness Act of 2000 (CUFFA). The agency will publish notice of these documents in the **Federal Register** at a later date for public comment. Until final regulations, directives, and appraisal guidelines are adopted, the Forest Service will determine recreation residence fees and manage recreation residence permits during the transition period consistent with (1) the provisions in section 614 of CUFFA, (2) current agency directives applicable to the administration of permits and assessment of fees for recreation residences, and (3) the direction contained in interim directive (ID) 2709.11-2003-1 issued to Forest Service Handbook (FSH) 2709.11, chapter 30.

Dated: February 12, 2003.

**Dale N. Bosworth,**

*Chief.*

[FR Doc. 03-4098 Filed 2-19-03; 8:45 am]

**BILLING CODE 3410-11-P**

## DEPARTMENT OF AGRICULTURE

### National Agricultural Statistics Service

#### Notice of the Advisory Committee on Agriculture Statistics Meeting

**AGENCY:** National Agricultural Statistics Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2, the National Agricultural Statistics Service (NASS) announces a meeting of the Advisory Committee on Agriculture Statistics.

**DATES:** The Advisory committee meeting will take place on February 24, 2003, from 8 a.m. to 5 p.m.

**ADDRESSES:** The meeting will take place at The Brown—A Camberley Hotel, 335 Broadway, Louisville, Kentucky. The public may file written comments before or within a reasonable time after the meeting to: Carol House, Executive Director, Advisory Committee on Agriculture Statistics, U.S. Department of Agriculture, National Agricultural Statistics Service, 1400 Independence Ave., SW., South Building, Room 4117, Washington, DC 20250–2000.

**FOR FURTHER INFORMATION CONTACT:** Carol House, Telephone: 202–720–4333, Fax: 202–720–9013, or e-mail: [chouse@nass.usda.gov](mailto:chouse@nass.usda.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Committee on Agriculture Statistics consists of 25 members appointed from 7 categories covering a broad range of agricultural disciplines and interests. During this meeting, the Advisory Committee will discuss: (1) Administrative Data, (2) Advisory Subcommittee for Hogs, (3) Publicity and Product Release Plan for the 2002 Census of Agriculture, and (4) Overview of the 2002 Census of Agriculture. The committee will observe and review NASS's data processing activities on Tuesday, February 25.

This advisory committee meeting will be open to the public. There will be an opportunity for public questions and comment during the meeting at 3:45 p.m. The public may file written comments to the USDA Advisory Committee contact person before or within a reasonable time after the meeting. All statements will become a part of the official records of the USDA Advisory Committee on Agriculture Statistics and will be kept on file for public review in the office of the Executive Director, Advisory Committee on Agriculture Statistics, U.S. Department of Agriculture, Washington, DC 20250.

Dated February 10, 2003, at Washington, DC.

**R. Ronald Bosecker,**  
*Administrator, National Agricultural Statistics Service.*

[FR Doc. 03–4030 Filed 2–19–03; 8:45 am]

**BILLING CODE 3410–20–P**

## DEPARTMENT OF AGRICULTURE

### National Agricultural Statistics Service

#### Notice of the Advisory Committee on Agriculture Statistics Hog Subcommittee Meeting

**AGENCY:** National Agricultural Statistics Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2, the National Agricultural Statistics Service (NASS) announces a meeting of the Advisory Committee on Agriculture Statistics Hog Subcommittee.

**DATES:** The subcommittee meeting will take place on February 25, 2003, from 2 p.m. to 5 p.m.

**ADDRESSES:** The meeting will take place at The Brown—A Camberley Hotel, 335 Broadway, Louisville, Kentucky. The public may file written comments before or within a reasonable time after the meeting to: Carol House, Executive Director, Advisory Committee on Agriculture Statistics, U.S. Department of Agriculture, National Agricultural Statistics Service, 1400 Independence Ave., SW., South Building, Room 4117, Washington, DC 20250–2000.

**FOR FURTHER INFORMATION CONTACT:** Carol House, Telephone: 202–720–4333, Fax: 202–720–9013, or e-mail: [chouse@nass.usda.gov](mailto:chouse@nass.usda.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Committee on Agriculture Statistics Hog Subcommittee consists of 3 members from the Advisory Committee on Agriculture Statistics and 8 members from hog industry. During this meeting, the Subcommittee will discuss the hog estimation program.

This Subcommittee meeting will be open to the public. There will be an opportunity for public questions and comments during the meeting at 3 p.m. The public may file written comments to the USDA Advisory Committee contact person before or within a reasonable time after the meeting. All statements will become a part of the official records of the USDA Advisory Committee on Agriculture Statistics and will be kept on file for public review in the office of the Executive Director, Advisory Committee on Agriculture Statistics, U.S. Department of Agriculture, Washington, DC 20250.

Dated February 10, 2003, at Washington, DC.

**R. Ronald Bosecker,**  
*Administrator, National Agricultural Statistics Service.*

[FR Doc. 03–4031 Filed 2–19–03; 8:45 am]

**BILLING CODE 3410–20–P**

## DEPARTMENT OF AGRICULTURE

### Rural Business-Cooperative Service

#### Notice Inviting Applications for Recognition as a State Rural Development Council

**AGENCY:** Rural Business-Cooperative Service (RBS), USDA.

**ACTION:** Notice inviting applications.

**SUMMARY:** This Notice invites applications for recognition as a State Rural Development Council (SRDC) pursuant to the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill). SRDCs are members of the National Rural Development Partnership (NRDP), more fully described elsewhere in this Notice. Applicants must meet the eligibility requirements in the 2002 Farm Bill and this Notice, submit an application for recognition, and submit evidence of ability to provide the requisite matching funds if federal funding is provided.

Recognition by the Secretary does not guarantee that a State Rural Development Council will automatically receive funding from the U.S. Department of Agriculture (USDA) or any other Federal agency, but will enable Federal agencies to make grants, gifts, contributions, provide technical assistance, or enter into contracts or cooperative agreements with the SRDC, in addition to making the SRDC automatically a part of the recomprised National Rural Development Partnership.

**DATES:** Applications must be submitted by 5 p.m. Eastern Time, April 21, 2003. Applications received after that date will be reviewed on a first come basis in order to receive Federal recognition. Applicants are encouraged to apply as soon as possible. Due to delays in the receipt of federal government mail through the U.S. Postal Service, applications should be sent by an express mail service (e.g., UPS, Federal Express).

**ADDRESSES:** Entities wishing to apply for assistance may download the application requirements delineated in this Notice from the NRDP Web site at: <http://www.rurdev.usda.gov/nrdp/nia.html>. Applicants may also request application packages from: Tia Trout, United States Department of Agriculture National Rural Development Partnership, MAIL STOP 3205, Room 4225, 1400 Independence Ave., SW., Washington, DC 20250–3205, telephone (202) 720–1534, e-mail [tia.trout@usda.gov](mailto:tia.trout@usda.gov).

**FOR FURTHER INFORMATION CONTACT:** Tia Trout, USDA National Rural

Development Partnership, MAIL STOP 3205, Room 4225, 1400 Independence Ave., SW., Washington, DC 20250-3205, telephone (202) 690-1534, e-mail [tia.trout@usda.gov](mailto:tia.trout@usda.gov). Information may also be obtained at the following Web site: <http://www.rurdev.usda.gov/nrdp>.

#### **SUPPLEMENTARY INFORMATION:**

##### **Programs Affected**

This program is listed in the Catalog of Federal Domestic Assistance under number 10.353. This program is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

##### **Information Collection and Recordkeeping Requirements**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), USDA invites comments on the information collection requirement in this notice. These requirements have been granted emergency clearance by the Office of Management and Budget under OMB Control Number 0570-0043.

Comments on this notice must be received by April 21, 2003.

Comments are invited on (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments on these information collections should refer to the OMB control number. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to Renita Bolden, Regulations and Paperwork Management Branch, Support Services Division, Rural Development, U.S. Department of Agriculture, STOP 0742, 1400 Independence Ave., SW., Washington, DC 20250-0742. Mail courier service deliveries requiring a street address delivery should be sent to the same attention at 300 E Street, SW., 3rd Floor, Washington, DC 20546.

*Title:* National Rural Development Partnership.

*Type of Request:* New collection.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 6.0 hours per Application.

*Respondents:* Joint proposals among public bodies, non profit and for-profit entities, including associations, in incorporated form or limited liability companies, tribal governments, and cooperatives.

*Estimated Number of Respondents:* 50.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Number of Responses:* 50.

*Estimated Total Annual Burden on Respondents:* 300 hours.

##### **Background**

The National Rural Development Partnership began in 1990 as a component of the President's Initiative on Rural America. Eight pilot SRDCs were formed in 1990; ten years later, 40 SRDCs were in place.

The 2002 Farm Bill authorizes the continuation of the National Rural Development Partnership, with a slightly modified membership structure. The Farm Bill specifies that membership in the reconstituted National Rural Development Partnership is to consist of a National Rural Development Coordinating Committee (NRDCC) and the SRDCs. The National Rural Development Coordinating Committee will be the subject of a separate appointment process and notice.

The 2002 Farm Bill statutorily recognizes the National Rural Development Partnership and authorizes appropriations specific to it and its members. The statute provides eligibility criteria for recognition as a State Rural Development Council. It is contemplated that the NRDP and its components (SRDCs and the NRDCC) will receive funding from a variety of sources: Federal, state, and private. USDA is responsible for recognizing, and entering into a recognition agreement with, each selected SRDC in accordance with statutory criteria.

Each SRDC that previously participated in the National Rural Development Partnership, and is interested in continuing to be recognized as an SRDC, must apply and be recognized pursuant to this Notice. New applicants are also invited to apply. Potential applicants within a state are encouraged to work together to develop a single application. Only one SRDC per state will be recognized.

A more extensive history can be found at the following Web site: <http://www.rurdev.usda.gov/nrdp/about>.

##### **Definitions**

*Funding Entity* refers to the responsible legal entity which is to receive, hold and disburse funds received from the National Rural Development Partnership for a SRDC.

*National Rural Development Partnership (NRDP)* refers jointly to recognized State Rural Development Councils and the National Rural Development Coordinating Committee.

*National Rural Development Coordinating Committee (NRDCC)* refers to a group to be composed of entities and representatives to be approved by the Secretary pursuant to a separate notice further implementing section 6021 of the 2002 Farm Bill.

*Rural Area* means all the territory of a State that is not within the boundaries of any standard metropolitan statistical area, and all territory within any standard metropolitan statistical area within a census tract having a population density of less than 20 persons per square mile, as determined by the Secretary according to the most recent census of the United States as of any date.

*State* includes each of the several States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and, to the extent the Secretary determines it to be feasible and appropriate, the Freely Associated States and the Federated States of Micronesia.

*State Rural Development Council (SRDC)* refers to an entity recognized as such by the Secretary in an agreement with USDA that confirms the Council meets the eligibility criteria in the 2002 Farm Bill.

*2002 Farm Bill* refers to Farm Security and Rural Investment Act, Public Law 107-171, enacted on May 13, 2002. Section 6021 of this Act authorizes the Secretary to continue the National Rural Development Partnership and authorizes appropriations for this program.

##### **Eligibility Requirements**

As specified in the 2002 Farm Bill, a State Rural Development Council shall:

1. Be composed of representatives of Federal, State, local and tribal governments, nonprofit organizations, regional organizations, the private sector, and other entities committed to rural advancement;

2. Operate with a nonpartisan and nondiscriminatory membership that is broad and representative of the economic, social, and political diversity of the state;

3. Have a structure such that the membership is responsible for the governance and operations of the SRDC; and

4. Provide matching funds, or in-kind goods or services, to support the activities of the SRDC, as more fully described below.

#### Recognition Agreement

SRDCs will enter into a Recognition Agreement with USDA. The Recognition Agreement will conform in all material respects to the form of agreement provided in Appendix A to this Notice, and will provide for a specific term of recognition. It will require compliance with any regulations as may be promulgated by USDA with respect to the NRD that are not in conflict with this Notice or any enforceable Recognition Agreement.

#### Duties post-Recognition

As specified in the 2002 Farm Bill, upon entering into a recognition agreement with USDA, the SRDC must:

1. Facilitate collaboration among Federal, State, local, and tribal governments and the private and nonprofit sectors in the planning and implementation of programs and policies that have an impact on rural areas of the State;

2. Monitor, report, and comment on policies and programs that address, or fail to address, the needs of the rural areas of the State;

3. In conjunction with the NRDCC, facilitate the development of strategies to reduce or eliminate conflicting or duplicative administrative or regulatory requirements of Federal, State, local, and tribal governments;

4. Provide to the NRDCC an annual plan with goals and performance measures; and

5. Submit to the NRDCC an annual report on the progress of the SRDC in meeting the goals and measures established in the annual plan.

Further, to assure continuing Farm Bill compliance, changes made to the SRDC's bylaws, organizational structure, rules of governance, or any other modifications that change the SRDC's structure or rules of operation must be provided to USDA immediately.

Each federally-funded SRDC must, as required by the NRDCC, submit an annual report to the NRDCC on the use of the funds, including a description of strategic plans, goals, performance measures and outcomes for the SRDC.

#### Contents of Application Package

A completed application must include the following:

(1) A brief description of the State Rural Development Council, including

the legal structure, membership categories (e.g., corporate, individual, government agency), and the responsible contact person.

(2) Organizational documents for the SRDC and, if different from the SRDC, the proposed Funding Entity. If the SRDC has 501(c)(3) not for profit corporation status, for example, the organizational documents would consist of the corporate charter and any other document that addresses the legal relationship among the members. If the SRDC has a legal structure other than a corporate form, the organizational documents must reflect how the SRDC was established and the legal relationship among the members.

(3) Rules of governance for the SRDC. The rules of governance must provide evidence that the membership is totally responsible for the governance and operations of the SRDC. If the SRDC has 501(c)(3) not for profit corporation status, for example, a copy of the bylaws must be provided. The RBS reserves the right to grant provisional recognition until June 30, 2004 to an SRDC applicant that must consult with other officials on limited governance matters.

(4) A representative list of members, which must identify a minimum of one, and a maximum of five, member(s) of the Council from each of the following six or (if applicable) seven institutional categories: (a) Federal government, (b) state government, (c) local government, (d) regional organizations, (e) not for profit corporations, (f) private for profit corporations, and (if applicable) (g) federally recognized tribal government. It is acceptable that some members on this representative list come from institutions committed to rural advancement that are not included in the aforementioned categories; such representatives should be placed in category (h) other entities committed to rural advancement (this could include colleges, universities, foundations, etc.). Provide the following information for each member person listed: Name, Institutional affiliation, Institutional category, Contact information (mailing address, telephone and fax numbers, and email address).

(5) A copy of the Council's written policy indicating that it operates in a nonpartisan and nondiscriminatory manner, or, in the alternative, a statement, signed by the Council Chair, indicating that the Council operates in a nonpartisan and nondiscriminatory manner.

(6) (a) A summary description of the key economic, social, and political regions of the rural areas of the state and (b) a summary description of how the Council represents the economic, social

and political make-up of the state's rural areas (e.g., cross-reference the members presented in item (4) above with the regions presented here). This section (6) of the application should not exceed two pages.

(7) Evidence that the SRDC is likely to have sufficient matching funds or in-kind goods or services for the period July 1, 2003 through May 13, 2007 to provide at least 33% in-kind or monetary match for any federal funds that might be provided under the provisions of the 2002 Farm Bill to cover SRDC activities during that period. Such evidence shall include letters of intent (or similar documents) from each organization that will provide matching funds or in-kind goods or services. For the period July 1, 2003 through June 30, 2004, these letters shall indicate intent to provide at least \$25,000 (in total, across all letters) in matching funds or in-kind goods or services. In addition, these letters shall indicate intent to provide additional matching funds or in-kind goods and services for the period July 1, 2004 through May 13, 2007.

#### Evaluation Considerations

The application materials will be reviewed to confirm that the basic eligibility criteria set forth in the 2002 Farm Bill are met. USDA may seek to independently verify that the representations made in the application are correct.

#### Application Selection Process

All applicants are encouraged to apply in a timely manner. Applications will be reviewed beginning April 21, 2003. An application may be submitted after this date subject to the proviso that it will not be considered if an SRDC for that State has already been granted recognition and remains in good standing under its Recognition Agreement. In the event that more than one application is received for a state, USDA will permit the applicants to work together to develop a single application that may be resubmitted, such that each state is represented by only one SRDC. In the event multiple applicants that are acceptable from one state do not wish to work together to develop a single application, USDA will choose one of those applicants to be the recognized SRDC. In this case, RBS will use the following criterion to choose the SRDC: Which applicant has the largest number of institutions represented as members (as reported in Item (4) above)? If two or more acceptable applicants are tied on that score, the tie-breaker will be: Which applicant has the largest match (as reported in Item (7) above)?

## What and Where to Submit

A complete, original application may be electronically sent as an e-mail attachment to [tia.trout@usda.gov](mailto:tia.trout@usda.gov). If applications are submitted electronically, a signature page must be submitted in hard copy or via fax. Alternatively, an original application package plus two paper copies may be submitted in hard copy to: Tia Trout, USDA National Rural Development Partnership, MAIL STOP 3205, Room 4225, 1400 Independence Ave., SW., Washington, DC 20250-3205.

Dated: February 3, 2003.

**John Rosso,**

*Administrator, Rural Business-Cooperative Service.*

## Appendix A

### Form of Recognition Agreement

Recognition Agreement Between [SRDC] and The United States Department of Agriculture (USDA)

#### Parties

SRDC Chair or Co-Chairs \_\_\_\_\_

SRDC Executive Director \_\_\_\_\_

USDA

Administrator—Rural Business-Cooperative Service

#### Purpose

The purpose of this Agreement is to confer recognition upon [SRDC] as the State Rural Development Council for the state of \_\_\_\_\_ a term ending May 13, 2007 unless earlier terminated for failure to maintain the requirements for ongoing eligibility pursuant to the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill).

#### Background

The National Rural Development Partnership authorized by section 6021 of the 2002 Farm Bill is composed of a National Rural Development Coordinating Committee (the Coordinating Committee) and State Rural Development Councils. The purposes of the Partnership are to empower and build the capacity of States and rural communities to design flexible and innovative responses to their own special rural development needs, with local determinations of progress and selection of projects and activities. Accordingly, the legislation requires that a State Rural Development Council (1) be composed of representatives of Federal, State, local, and tribal governments, nonprofit organizations, regional organizations, the private sector, and other entities committed to rural advancement, (2) have a nonpartisan and nondiscriminatory membership that is broad and representative of the economic, social, and political diversity of the State, and (3) that the membership shall be responsible for the governance and operations of the State Rural Development Council.

#### Agreement

The [SRDC] hereby represents the following:

1. The membership of the SRDC meets and will continue to meet on an ongoing basis the

eligibility requirements for recognition as a member of the NRDP set forth in the 2002 Farm Bill.

2. The entity which shall undertake fiscal responsibilities on behalf of the SRDC for purposes of any USDA funding is [name of Funding Entity/Address]. The officer who is authorized to enter into agreements on behalf of the Funding Entity is [Name, Title].

3. The person who is authorized to represent the SRDC in meetings of the NRDP and enter into contracts and receive notices on behalf of the SRDC is: [Name, Title, Address]

The [SRDC] hereby undertakes to perform the following duties:

1. Facilitate collaboration among Federal, State, local, and tribal governments and the private and nonprofit sectors in the planning and implementation of programs and policies that have an impact on rural areas of the State;

2. Monitor, report, and comment on policies and programs that address, or fail to address, the needs of the rural areas of the State; and

3. As part of the NRDP, in conjunction with the Coordinating Committee, facilitate the development of strategies to identify and reduce or eliminate conflicting or duplicative administrative or regulatory requirements of Federal, State, local, and tribal governments.

Furthermore, the [SRDC] agrees to:

(a) Provide to the Coordinating Committee an annual plan with goals and performance measures; and

(b) Submit to the Coordinating Committee an annual report on the progress of the [SRDC] in meeting the goals and measures.

The [SRDC] hereby agrees to provide matching funds or in-kind goods or services, as required by statute, to support the activities of the undersigned, in an amount that is at least 33 percent of the amount of Federal funds received from a Federal agency, except where the Federal funds in question are (a) to support one or more specific programs or project activities or (b) to reimburse the SRDC for services provided to the funding Federal agency.

The [SRDC] hereby agrees to provide evidence on an on-going basis that the SRDC is in compliance with this Agreement. For example, as and when the Council modifies its bylaws, organizational structure, rules of governance, and/or makes any other modifications that change the SRDC's structure or rules of operations, such changes must be provided to USDA immediately.

Furthermore, the [SRDC] understands that if it applies to USDA—RD for federal funding for its core operations, it must comply with all federal requirements regarding financial management, good standing, criminal convictions, debarment, civil rights and any other applicable laws.

#### Recognition

The USDA hereby recognizes [name of SRDC] as a State Rural Development Council and member of the National Rural Development Partnership. All correspondence shall be directed to USDA, care of [David Sears, National Partnership Office, email, telephone].

Programming, Budgeting, Funding, and Reimbursement Arrangement

This Recognition Agreement does not commit USDA or the federal government to provide any financial assistance.

#### Authority

The USDA authority for entering into this Recognition Agreement is Section 6021 of Public Law 107-171 (May 13, 2002). This Recognition Agreement is subject to Section 6021 of the 2002 Farm Bill, the Notice Inviting Applications for Recognition, future SRDC regulations not otherwise inconsistent with this Recognition Agreement and all other applicable laws.

#### Approvals

The signatories hereby certify that they have the authority to enter into this Recognition Agreement.

#### Revocation

Upon written notice from USDA of a failure to perform or other default under this Agreement, the SRDC has 90 days from the date of the USDA written notice to cure the failure to perform or the default. USDA may terminate this agreement, thereby revoking recognition, upon written notice to the SRDC for failure of the SRDC to cure a failure to perform or otherwise cure a default under this Recognition Agreement.

The SRDC may terminate this Recognition Agreement upon 90 days written notice to USDA.

#### Effective Date

This Recognition Agreement will become effective upon the signature of all parties and shall remain in effect until the earlier of May 13, 2007 or termination by either party. Its provisions can be amended or supplemented in writing as may be agreed upon.

\_\_\_\_\_  
Administrator  
Rural Business-Cooperative Service  
Administrator

\_\_\_\_\_  
[Date]

\_\_\_\_\_  
[ ] Chair  
SRDC

\_\_\_\_\_  
[Date]

\_\_\_\_\_  
[ ] Executive Director  
SRDC

\_\_\_\_\_  
[Date]

[FR Doc. 03-4040 Filed 2-19-03; 8:45 am]

BILLING CODE 3410-XY-P

## DEPARTMENT OF COMMERCE

[Docket No.: 030213030-3030-01]

### Office of the General Counsel; Guidelines for the Proper Consideration of Small Entities in Rulemaking

**AGENCY:** Office of the General Counsel, Department of Commerce.

**ACTION:** Notice of availability.



**SUMMARY:** The Department of Commerce (Department) announces the availability of its guidelines for the proper consideration of small entities in agency rulemaking pursuant to Executive Order 13272. The purpose of these guidelines is to establish procedures and policies to promote compliance with the Regulatory Flexibility Act of 1980 (RFA). These guidelines ensure that the Department properly considers the potential impacts of its rulemakings on small business, small governmental jurisdictions, and small organizations during the rulemaking process.

**ADDRESSES:** To obtain a copy of the Department's guidelines, please send a written request to Daniel Cohen, Chief Counsel for Regulation, Office of the Assistant General Counsel for Legislation and Regulation, U.S. Department of Commerce, 1401 Constitution Ave., Suite 5876, Washington, DC 20230, or visit the following Web site: <http://www.ogc.doc.gov/ogc/legreg/regulati.htm>.

**FOR FURTHER INFORMATION CONTACT:** For further information, please contact Tricia Choe, Attorney-Advisor, Office of the Assistant General Counsel for Legislation at (202) 482-4265.

**SUPPLEMENTARY INFORMATION:** On August 13, 2002, the President signed Executive Order 13272 entitled Proper Consideration of Small Entities in Agency Rulemaking. Executive Order 13272 requires federal agencies to issue policies and procedures to ensure that the potential impacts of agency rules in small businesses, small organizations, and small governmental jurisdictions are properly considered during the rulemaking process consistent with the statutory mandates of the Regulatory Flexibility Act of 1980 (RFA). *See* 5 U.S.C. 601 *et seq.* The intent of the Order is to ensure that agencies work closely with the Office of Advocacy at the Small Business Administration to address small business issues as early as possible in the regulatory process, particularly as they relate to disproportionate regulatory burden.

Pursuant to the requirements of the Order, the Department of Commerce prepared guidelines that establish procedures and policies ensuring compliance with the RFA. These guidelines ensure that the Department properly considers the potential impacts of rules on small business, small governmental jurisdictions, and small organizations during the rulemaking process. Specifically, the document provides guidance concerning the formulation of the initial regulatory flexibility analysis and final regulatory

flexibility analysis, the certification process, and the SBA review process.

On November 13, 2002, the Department submitted a draft of the guidelines to SBA for review and comment. After reviewing the guidelines, SBA requested that the Department make minor editorial revisions and include the Department's procedure for notifying SBA of proposed rules that may have a significant economic impact on a substantial number of small entities. The Department addressed all of SBA's comments. The Department now makes available to the public its guidelines. To obtain a copy of the guidelines, please see the **ADDRESSES** section of this notice.

Dated: February 13, 2003.

**Theodore W. Kassinger,**  
General Counsel, Department of Commerce.  
[FR Doc. 03-4032 Filed 2-19-03; 8:45 am]  
**BILLING CODE 3510-BW-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-201-809]

#### **Certain Cut-to-Length Carbon Steel Plate From Mexico: Notice of Final Court Decision and Amended Final Results of Antidumping Duty Administrative Review**

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Final Court Decision and Amended Final Results of Antidumping Duty Administrative Review.

**SUMMARY:** On November 12, 2002, the United States Court of International Trade (CIT) affirmed the remand determination of the Department of Commerce (the Department) in the 1997-98 administrative review for Altos Hornos de Mexico, S.A. de C.V. (AHMSA) arising from the antidumping duty order on certain cut-to-length carbon steel plate from Mexico. *See Altos Hornos de Mexico, S.A. de C.V. v. United States of America, Bethlehem Steel Corporation and United States Steel Corporation*, Consol. Ct. No. 01-00018, Slip Op. 02-136 (CIT November 12, 2002) (the November 12, 2002 Court order). As there is now a final court decision, we are amending the amended final results of the review in this matter. We will instruct the U.S. Customs Service to liquidate entries subject to these amended final results.

**EFFECTIVE DATE:** February 20, 2003.

#### **FOR FURTHER INFORMATION CONTACT:**

Thomas Killiam or Michael Heaney, Antidumping/Countervailing Duty Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street N.W. and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482-5222 or (202) 482-4475, respectively.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

On August 19, 1993, the Department published the antidumping duty order on steel plate from Mexico (58 FR 44165). On February 18, 2000, the Department published the final results of the 1997-1998 administrative review. *See Certain Cut-to-Length Carbon Steel Plate From Mexico: Final Results of Antidumping Duty Administrative Review*, 65 FR 8338, February 18, 2000. The Department published three successive sets of amended results, on November 2, 2000 (65 FR 65830), December 12, 2000 (65 FR 77566), and January 24, 2001 (66 FR 7619).

Following the January 24, 2001 amended results, the foreign producer, AHMSA, contested certain aspects of the Department's final and amended final results at the CIT. The Department requested a voluntary remand, and on April 15, 2002, the CIT remanded the amended final results to the Department. On June 28, 2002, the Department issued its remand redetermination. *See Redetermination Pursuant to Court Remand Order in Altos Hornos de Mexico, S.A. de C.V. v. United States, et. al.*, Court No. 01-00018, June 28, 2002. *See also* Memorandum to the File from T. Killiam, Case Analyst, "Analysis of Programming Revisions in the Final Remand Results of Review of Cut-to-Length Carbon Steel Plate from Mexico A-201-809", June 28, 2002; and Memorandum to Neal Halper, Director, Office of Accounting, from Peter S. Scholl, Senior Accountant, "Final Remand Redetermination - Antidumping Duty Administrative Review of Certain Cut-to-Length Carbon Steel Plate from Mexico," June 28, 2002. In the remand determination, the Department used historical and inflation-adjusted information previously placed on the record by AHMSA to calculate a revised financial expense rate, and applied this revised rate to AHMSA's historical cost of manufacturing.

On November 12, 2002, the CIT sustained the Department's remand results.



**Amendment to Final Results**

The time period for appealing the CIT's decision sustaining the Department's remand results has expired and no party has appealed this decision. Therefore, pursuant to section 516 A(c) of the Tariff Act, (19 U.S.C. 1516a(c)), we are amending our final results of review for the period August 1, 1997 through July 1, 1998, to reflect the findings in the remand results.

The revised weighted-average margin for AHMSA is as follows:

Manufacturer/Exporter	Margin (percent)
AHMSA .....	0.07 ( <i>de minimis</i> )

The Department will issue appraisal instructions directly to Customs to liquidate without regard to antidumping duties all entries of AHMSA's subject merchandise during the POR, as provided in 19 C.F.R. 351.106(c)(2). The above amended rate will not affect AHMSA's cash deposit rates currently in effect, which continue to be based on the margins found to exist in the most recently completed review.

We are issuing and publishing this determination in accordance with section 751(a)(1) of the Tariff Act, (19 U.S.C. 1675(a)(1)).

Dated: February 11, 2003.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 03-4131 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-DS-S**

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A-588-861]

**Notice of Preliminary Determination of Sales at Less Than Fair Value: Polyvinyl Alcohol from Japan**

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Preliminary Determination of Sales at Less Than Fair Value.

**SUMMARY:** We preliminarily determine that polyvinyl alcohol from Japan is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733(b) of the Tariff Act of 1930, as amended.

Interested parties are invited to comment on this preliminary determination. We will make our final determination not later than 75 days

after the date of this preliminary determination.

**EFFECTIVE DATE:** February 20, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Mike Strollo or Gregory E. Kalbaugh, Office of AD/CVD Enforcement, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-0629 or (202) 482-3693, respectively.

**SUPPLEMENTARY INFORMATION:****Preliminary Determination**

We preliminarily determine that polyvinyl alcohol (PVA) from Japan is being sold, or is likely to be sold, in the United States at less than fair value (LTFV), as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins of sales at LTFV are shown in the "Suspension of Liquidation" section of this notice.

**Case History**

Since the initiation of this investigation (*Initiation of Antidumping Duty Investigations: Polyvinyl Alcohol from Germany, Japan, the People's Republic of China, the Republic of Korea, and Singapore*, 67 FR 61591 (Oct. 1, 2002)) (*Initiation Notice*), the following events have occurred:

On September 30, 2002, we received scope comments from Celanese Ltd. and E.I. DuPont de Nemours & Co. (collectively, the petitioners), in which the petitioners requested that we revise the scope to exclude PVA used as, or in the manufacture of, excipients.

On October 11, 2002, the petitioners and two Japanese producers, Kuraray Co., Ltd. (Kuraray) and Marubeni Specialty Chemicals, Inc. (Marubeni), submitted comments on the model-matching criteria to be used by the Department. On October 15, 2002, Marubeni submitted an amendment to its model-matching comments.

On October 21, 2002, we received requests to exclude certain additional products from the scope of this investigation from Kuraray and two importers of PVA (*i.e.*, Oxyvinyls, LP and Ricoh Electronics, Inc.).

Also on October 21, 2002, the United States International Trade Commission (ITC) preliminarily determined that there is a reasonable indication that imports of PVA from Japan are materially injuring the United States industry. *See* ITC Investigation Nos. 731-TA-1014-1018 (Publication No. 3553, *Polyvinyl Alcohol from Germany, Japan, the People's Republic of China, the Republic of Korea, and Singapore*, 67 FR 65597 (Oct. 25, 2002)).

On October 22, 2002, we issued antidumping questionnaires to Denki Kagaku Kogyo Kabushiki Kaisha (Denki Kagaku), Japan VAM & POVAL Co., Ltd. (Japan VAM & POVAL), Kuraray, and the Nippon Synthetic Chemical Industry Co., Ltd. (Nippon Gohsei), the producers/exporters accounting for all known exports of subject merchandise from Japan during the period of investigation (POI). For further discussion, see the memorandum to Louis Apple, Director, Office 2, from the Team entitled "Antidumping Duty Investigation of Polyvinyl Alcohol from Japan - Selection of Respondents," dated October 22, 2002.

On November 19, 2002 and November 25, 2002, respectively, Kuraray and Nippon Gohsei submitted responses to Section A of the Department's questionnaire. Both Japan VAM & POVAL and Denki Kagaku failed to respond to the Department's questionnaire. For further discussion, see the "Facts Available (FA)" section of this notice.

On December 5, 2002, Kuraray notified the Department that it would no longer participate in this investigation, and it requested that the Department remove all of its business proprietary information from the record of this proceeding. On December 11, 2002, the Department destroyed Kuraray's business proprietary information and notified Kuraray of this action. For further discussion, see the "Facts Available (FA)" section of this notice.

On December 13, 2002, the petitioners and Nippon Gohsei submitted additional model-matching comments.

On December 23, 2002, the petitioners agreed to the exclusion requests made on October 21, 2002. On January 9, 2003, Kuraray requested that the Department modify the scope language in the petitioners' December 23, 2002, submission to avoid unnecessary restrictions on imports of certain of the products covered by that submission which are not manufactured in the United States. On January 22, 2003, the petitioners agreed to the majority of Kuraray's proposed revisions. Accordingly, certain exclusions have now been incorporated into the scope. For further discussion, see the "Scope Comments" section below.

On January 27, 2003, Japan VAM & POVAL requested that the Department revise the scope to exclude certain additional copolymers. Also on January 27, 2003, Nippon Gohsei requested that the Department modify the scope language in the petitioners' December 23, 2002, submission to avoid unnecessary restrictions on imports of the remaining copolymers covered by

that submission not addressed in Kuraray's January 9, 2003, letter. On February 4, 2003, the petitioners agreed to all of the revisions requested by Nippon Gohsei, and an additional revision requested by Kuraray. On February 5, 2003, the petitioners submitted a letter noting that they were in the process of reviewing Japan VAM & POVAL's exclusion request, and had not yet agreed to the exclusion request. Because there was insufficient time to properly consider Japan VAM & POVAL's exclusion request, we will address it in the final determination.

In December 2002 and January 2003, we received responses to the remaining sections of the Department's original questionnaire, as well as certain supplemental questionnaires, from Nippon Gohsei.

#### Period of Investigation

The POI is July 1, 2001, through June 30, 2002. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition (*i.e.*, September 2002).

#### Scope of Investigation

The merchandise covered by this investigation is PVA. This product consists of all PVA hydrolyzed in excess of 80 percent, whether or not mixed or diluted with commercial levels of defoamer or boric acid, except as noted below.

The following products are specifically excluded from the scope of this investigation:

- 1) PVA in fiber form.
- 2) PVA with hydrolysis less than 83 mole percent and certified not for use in the production of textiles.
- 3) PVA with hydrolysis greater than 85 percent and viscosity greater than or equal to 90 cps.
- 4) PVA with a hydrolysis greater than 85 percent, viscosity greater than or equal to 80 cps but less than 90 cps, certified for use in an ink jet application.
- 5) PVA for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement, and accompanied by an end-use certification.
- 6) PVA covalently bonded with cationic monomer uniformly present on all polymer chains in a concentration equal to or greater than one mole percent.
- 7) PVA covalently bonded with carboxylic acid uniformly present on all polymer chains in a concentration equal to or greater than two mole percent, certified for use in a paper application.
- 8) PVA covalently bonded with thiol uniformly present on all polymer chains, certified for use in emulsion

polymerization of non-vinyl acetic material.

9) PVA covalently bonded with paraffin uniformly present on all polymer chains in a concentration equal to or greater than one mole percent.

10) PVA covalently bonded with silan uniformly present on all polymer chains certified for use in paper coating applications.

11) PVA covalently bonded with sulfonic acid uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

12) PVA covalently bonded with acetoacetylate uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

13) PVA covalently bonded with polyethylene oxide uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

14) PVA covalently bonded with quaternary amine uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

The merchandise under investigation is currently classifiable under subheading 3905.30.00 of the *Harmonized Tariff Schedule of the United States* (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

#### Scope Comments

In accordance with the preamble to our regulations (*see Antidumping Duties; Countervailing Duties*, 62 FR 27296, 27323 (May 19, 1997)), we set aside a period of time for parties to raise issues regarding product coverage and encouraged all parties to submit comments within 20 calendar days of publication of the initiation notice. *See the Initiation Notice*, 67 FR at 61591.

On September 30, 2002, the petitioners requested that we exclude PVA used as, or in the manufacture, of excipients.

On October 21, 2002, Kuraray and two importers of PVA (*i.e.*, Ricoh Electronics and Oxyvinyls) requested that the Department also revise the scope to exclude various PVA products with specific physical characteristics and/or specific end-uses. These products included: 1) C-polymers - certain copolymers of PVA and cationic monomer; 2) K-polymers - certain copolymers of PVA and carboxylic acid for use in a paper application; 3) M-polymers - certain copolymers of PVA and thiol for use in emulsion

polymerization of non-vinyl acetic material; 4) MP-polymers - certain copolymers of PVA and paraffin; 5) R-polymers - certain copolymers of PVA and silan that are used in paper coating applications; and 6) PVA hydrolyzed at less than 83 percent. Each of the exclusion requests specified ranges of hydrolysis and viscosity and maximum levels of volatiles and ash, by weight.

On December 23, 2002, the petitioners agreed to these requests, shown as items 2, 3, and 5 through 13 in the "Scope of Investigation" section above, and modified as noted below.

On January 9, 2003, Kuraray requested that the Department broaden these exclusions to cover certain additional products not produced in the United States. Specifically, Kuraray requested that the scope exclusions agreed to by the petitioners with respect to certain copolymer products specify a minimum percentage of the non-PVA monomers present in these copolymer products outlined above (*i.e.*, cationic monomer, carboxylic acid, thiol, and paraffin) instead of specifying exact levels of hydrolysis, viscosity, volatiles, and ash content as noted in the petitioners' December 23, 2002, submission.

On January 22, 2003, the petitioners agreed to the majority of the modifications proposed by Kuraray. Specifically, with respect to copolymers of PVA and carboxylic acid, the petitioners agreed to remove the specifications for hydrolysis, viscosity, volatiles, and ash content from the proposed exclusion language. However, the petitioners did not agree to change the end-use requirement in the proposed exclusion from "certified for use in a paper application" to "certified not for use in the production of textiles." With respect to copolymers of PVA and paraffin, the petitioners agreed to remove the specification for hydrolysis, viscosity, volatiles, and ash content from the proposed exclusion language. However, the petitioners did not agree to change the concentration level of the additional monomer from one percent to 0.5 percent (or lower). Finally, the petitioners agreed to lower the viscosity level of homopolymers hydrolyzed greater than 85 percent from 90 to 80 centipoise, provided that, when the product has a viscosity of greater than or equal to 80 centipoise and less than 90 centipoise, it is certified for use in an ink-jet application. Accordingly, certain exclusions have now been incorporated into the scope. *See the "Scope of the Investigation" section above.*

On January 27, 2003, Japan VAM & POVAL, one of the mandatory

respondents who has not responded to the Department's questionnaire, requested that the Department revise the scope to exclude certain PVA products with specific physical characteristics and/or specific end-uses. These products include: D-copolymers (*i.e.*, certain copolymers of PVA and diacetoneacrylamide) for use in a paper application.

Additionally, on January 27, 2003, Nippon Gohsei requested that the remaining scope exclusions agreed to by the petitioners but not addressed in Kuraray's January 9, 2003, submission specify a minimum percentage of the non-PVA monomers (*i.e.*, sulfonic acid, acetoacetylate, polyethylene oxide, or quaternary amine) instead of specifying exact levels of hydrolysis, viscosity, volatiles, and ash content as noted in the petitioners' December 23, 2002, submission.

On February 4, 2003, the petitioners agreed to all of the revisions requested by Nippon Gohsei. In addition, the petitioners also agreed to revise the scope to exclude certain copolymers covalently bonded with silan uniformly present on all polymer chains in a concentration equal to or greater than one mole percent, certified for use in paper coating applications, pursuant to a request made by Kuraray.

As noted above, on February 5, 2003, the petitioners submitted a letter noting that they were in the process of reviewing Japan VAM & POVAL's exclusion request, and had not yet agreed to the exclusion request. Because there was insufficient time to properly consider Japan VAM & POVAL's exclusion request, we will address it in the final determination.

#### Facts Available (FA)

##### 1. Application of FA

Section 776(a)(2) of the Act provides that if an interested party (A) withholds information requested by the Department, (B) fails to provide such information by the deadline, or in the form or manner requested, (C) significantly impedes a proceeding, or (D) provides information that cannot be verified, the Department shall use, subject to sections 782(d) and (e) of the Act, facts otherwise available in reaching the applicable determination.

Pursuant to section 782(e) of the Act, the Department shall not decline to consider submitted information if all of the following requirements are met: (1) The information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the

applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability; and (5) the information can be used without undue difficulties.

On October 22, 2002, the Department issued its questionnaire to Denki Kagaku, Japan VAM & POVAL, and Kuraray. Neither Denki Kagaku nor Japan VAM & POVAL responded to the Department's questionnaires. Moreover, on December 5, 2002, Kuraray informed the Department that it did not intend to participate in this investigation. Because these companies failed to supply necessary information, we have applied FA to calculate their dumping margins, pursuant to section 776(a)(2)(B) of the Act.

##### 2. Selection of Adverse FA (AFA)

In selecting from among the facts otherwise available, section 776(b) of the Act authorizes the Department to use an adverse inference if the Department finds that an interested party failed to cooperate by not acting to the best of its ability to comply with the request for information. *See, e.g., Notice of Final Determination of Sales of Less Than Fair Value and Final Negative Critical Circumstances: Carbon and Certain Alloy Steel Wire Rod from Brazil*, 67 FR 55792, 55794–96 (Aug. 30, 2002). Each of the respondents was notified in the Department's questionnaires that failure to submit the requested information by the date specified might result in use of FA. As a general matter, it is reasonable for the Department to assume that Denki Kagaku, Japan VAM & POVAL, and Kuraray possessed the records necessary for this investigation and that by not supplying the information the Department requested, these companies failed to cooperate to the best of their ability. As the respondents failed to cooperate to the best of their ability, we are applying an adverse inference pursuant to section 776(b) of the Act.

##### 3. Corroboration of Information

Section 776(b) of the Act authorizes the Department to use as AFA information derived from the petition, the final determination from the LTFV investigation, a previous administrative review, or any other information placed on the record.

Section 776(c) of the Act requires the Department to corroborate, to the extent practicable, secondary information used as FA. Secondary information is defined as “{i}nformation derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review

under section 751 concerning the subject merchandise.” *See* Statement of Administrative Action (SAA) accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–316 at 870 (1994) and 19 CFR 351.308(d).

The SAA clarifies that “corroborate” means that the Department will satisfy itself that the secondary information to be used has probative value. *See* the SAA at 870. The SAA also states that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation. *Id.*

In order to determine the probative value of the margins in the petition for use as AFA for purposes of this determination, we examined evidence supporting the calculations in the petition. We reviewed the adequacy and accuracy of the information in the petition during our pre-initiation analysis of the petition, to the extent appropriate information was available for this purpose. *See* the September 25, 2002, *Initiation Checklist*, on file in the Central Records Unit, Room B-099, of the Main Commerce Department building, for a discussion of the margin calculations in the petition. In accordance with section 776(c) of the Act, to the extent practicable, we examined the key elements of the export price (EP) and normal value (NV) calculations on which the margins in the petition were based.

In selecting from among the facts otherwise available and using an adverse inference, we reviewed the information provided in the petition and in the response submitted by Nippon Gohsei. The petition contained a margin calculation for each of two products sold by Kuraray. *See* below for a review of the methodology used by the petitioners for their calculations of EP and NV. Because these margins were higher than the margin that we calculated for Nippon Gohsei, we selected these margins for purposes of corroboration.

#### Export Price

With respect to the margins in the petition, EP was based on POI price quotes for the sale of PVA produced by Kuraray to customers in the United States. The petitioners calculated net U.S. prices for PVA by deducting a distributor mark-up, where applicable, and certain movement charges.

We corroborated the U.S. prices from the petition by comparing them to prices of comparable products sold by Nippon Gohsei. We found that Nippon

Gohsei made U.S. sales of comparable products at similar prices to the U.S. prices from the petition, thus corroborating the prices provided in the petition. For ocean freight expense, we likewise found that the petition contained the same expense for each of the two products and that sales by Nippon Gohsei with ocean freight in excess of these amounts of expenses were sufficient to corroborate the amounts provided in the petition. We were unable to corroborate the U.S. inland freight charges from the petition since no such charges were reported by Nippon Gohsei. The Department was provided with no useful information by the respondents or other interested parties and is aware of no other independent sources of information that would enable us to further corroborate the EP calculations in the petition. Specifically, we attempted to locate inland freight charges through publicly available sources, but we were unable to do so.

It is worth noting that the implementing regulation for section 776 of the Act states, "(t)he fact that corroboration may not be practicable in a given circumstance will not prevent the Secretary from applying an adverse inference as appropriate and using secondary information in question." See 19 CFR 351.308(d). Additionally, the SAA specifically states that where "corroboration may not be practicable in a given circumstance, the Department need not prove that the facts available are the best alternative information." See the SAA at 870. For further discussion, see the February 12, 2003, memorandum to the file from the team entitled "Corroboration of Data Contained in the Petition for Assigning Facts Available Rates" (Corroboration Memo).

#### Normal Value

The petitioners based NV on home market price quotes from Kuraray for PVA of a comparable grade to the products exported to the United States. These price quotes were contemporaneous with the U.S. price quotes used as the basis for EP. In addition, the petitioners alleged that sales of PVA products in the home market were made at prices below the fully absorbed cost of production (COP), within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation. Based upon a comparison of the prices of the foreign like product in the home market to the calculated COP of the product, we found reasonable grounds to believe or suspect that sales of the foreign like

product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department initiated a country-wide cost investigation. Pursuant to section 773(b)(3) of the Act, COP consisted of the cost of manufacture (COM), selling, general and administrative (SG&A) expenses, and packing. The petitioners calculated COP based on the experience of a U.S. PVA producer during the 2001 fiscal year, adjusted for known differences between costs incurred to manufacture PVA in the United States and Japan.

Pursuant to sections 773(a)(4), 773(b) and 773(e) of the Act, the petitioners based NV for sales in Japan on constructed value (CV). The petitioners calculated CV using the same COM, SG&A and financial expense figures used to compute the COP. Consistent with section 773(e)(2) of the Act, the petitioners included in CV an amount for profit. For profit, the petitioners relied upon the amount reported in Kuraray's 2001 financial statements.

We found that Nippon Gohsei made sufficient home market sales at prices similar to the home market prices provided in the petition. One COP amount was provided in the petition for the two products sold by Kuraray. We were able to corroborate this amount, since the highest COP reported by Nippon Gohsei for a comparable product was similar to the COP provided in the petition. For further discussion, see the Corroboration Memo.

Therefore, based on our efforts, described above, to corroborate information contained in the petition, and in accordance with 776(c) of the Act, we consider the margins in the petition to be corroborated to the extent practicable for purposes of this preliminary determination.

Accordingly, in selecting AFA with respect to Denki Kagaku, Japan VAM & POVAL, and Kuraray, we have applied the margin rate of 144.16 percent, which is the highest estimated dumping margin set forth in the notice of initiation. See the *Initiation Notice*, 67 FR at 61593.

#### Fair Value Comparisons

To determine whether sales of PVA from Japan to the United States were made at less than fair value, we compared the EP to the NV, as described in the "Export Price" and "Normal Value" sections of this notice, below. In accordance with section 777A(d)(1)(A)(i) of the Act, we compared POI weighted-average EPs to weighted-average NVs.

#### Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced and sold by Nippon Gohsei in the home market during the POI that fit the description in the "Scope of Investigation" section of this notice to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We compared U.S. sales to sales made in the home market, where appropriate. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade, based on the characteristics discussed below.

In October 2002, Kuraray, Marubeni, and the petitioners submitted comments on the model-matching criteria to be used by the Department. Based on these comments, we proposed to match products sold in the United States to products sold in the home market in the ordinary course of trade that were identical with respect to the following hierarchy of characteristics: molecular structure, hydrolysis, viscosity, degree of modification, particle size, tackifier, defoamer, ash, color, volatiles, and visual impurities. We invited interested parties to submit additional comments on these criteria prior to the preliminary determination.

In December 2002, the petitioners requested that the Department revise the proposed model-matching hierarchy to place hydrolysis and viscosity as the most important criteria.

Also in December 2002, Nippon Gohsei requested the Department revise the particle size field of the hierarchy to include PVA in standard, fine, pellet, and liquid forms. In addition, Nippon Gohsei requested that the Department add the field SOLH/U in order to distinguish between PVA sold in dry form versus liquid form. Finally, Nippon Gohsei requested that the Department allow respondents to report hydrolysis, viscosity, and degree of modification in ranges.

After analyzing these comments, we have reconsidered the model-matching hierarchy and revised it as follows: 1) we added as the most important criterion whether the product is a homo- or a co- polymer; 2) we placed hydrolysis and viscosity before molecular structure (*i.e.*, the type of copolymer); 3) we accepted the proposed changes to particle size field suggested by Nippon Gohsei; and 4) we allowed the reporting of hydrolysis, viscosity, and degree of modification in

ranges. All other characteristics remained the same. For further discussion, see the memorandum entitled "Concurrence Memorandum for the Preliminary Determination in the Investigation of Polyvinyl Alcohol from Japan," dated February 12, 2003 (the Concurrence Memorandum), on file in room B-099 of the Department's Central Records Unit (CRU).

### Export Price

In accordance with section 772(a) of the Act, we based our calculations on EP because the subject merchandise was sold by the producer or exporter directly to the first unaffiliated purchaser prior to importation. In cases where Nippon Gohsei sold pursuant to multiple-shipment sales agreements, we used the date of the sales agreement, where available, as the date of sale. Where the date of the sales agreement was not known, we used the date of shipment as the date of sale because this date preceded the date of invoice. For further discussion, see the Concurrence Memo.

We based EP on the packed delivered prices to unaffiliated purchasers in either Japan or the United States. Where appropriate, we made adjustments for billing errors. We also made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign brokerage and handling, loading expenses, international freight, and marine insurance.

### Normal Value

#### A. Home Market Viability

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.*, the aggregate volume of home market sales of the foreign like product is equal to or greater than five percent of the aggregate volume of U.S. sales), we compared the respondent's volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act. Because the respondent's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales for the subject merchandise, we determined that the home market was viable for the respondent.

#### B. Affiliated-Party Transactions and Arm's-Length Test

Nippon Gohsei reported sales of the foreign like product to affiliated end-users. To test whether these sales to

affiliated customers were made at arm's length, where possible, we compared the prices of sales to affiliated and unaffiliated customers, net of all movement charges, direct selling expenses, and packing. Where the price to the affiliated party was, on average, 99.5 percent or more of the price to unaffiliated parties, we determined that sales made to the affiliated party were at arm's length. Consistent with section 351.403(c) of the Department's regulations, we excluded from our analysis those sales where the price to the affiliated parties was less than 99.5 percent of the price to the unaffiliated parties.

#### C. Cost of Production Analysis

Based on our analysis of an allegation contained in the petition, we found that there were reasonable grounds to believe or suspect that sales of PVA in the home market were made at prices below their COP. Accordingly, pursuant to section 773(b) of the Act, we initiated a country-wide sales-below-cost investigation to determine whether sales were made at prices below their respective COPs. See the *Initiation Notice*, 67 FR at 61594.

##### 1. Calculation of COP

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of the cost of materials and fabrication for the foreign like product, plus an amount for general and administrative expenses (G&A), including interest expenses. See the "Test of Home Market Sales Prices" section below for treatment of home market selling expenses. We relied on the COP data submitted by Nippon Gohsei, except as noted below:

- We revised the reported costs for raw materials and utilities obtained from an affiliated party using facts available because Nippon Gohsei failed to report either the affiliate's costs and/or the market price for these inputs, as required by section 773(f)(3) of the Act (*i.e.*, the "major input" rule). Because Nippon Gohsei stated that it attempted to obtain the necessary cost data from its affiliate but was unable to compel its affiliate to provide this information, we have used "gap-filler" facts available for the affiliate's costs and/or a market price in accordance with our practice. See *Notice of Final Determination of Sales at Less Than Fair Value: Certain Polyester Staple Fiber From the Republic of Korea*, 65 FR 16880 (Mar. 30, 2000) and accompanying Issues and Decision Memorandum at *Comment 6*. As "gap-filler" facts available, we derived a cost and/or a market price for these inputs using data contained in the

petition. We then used the higher of these costs, the market price, or the reported transfer prices, in accordance with section 773(f)(3) of the Act.

- We included the total amount of research and development expense incurred by Nippon Gohsei during the cost reporting period in the G&A rate calculation. We also included gain and loss on sale of fixed assets, and other operating incomes and expenses in the G&A rate calculation.

For further discussion, see the memorandum from Sheikh M. Hannan to Neal Halper, Director, Office of Accounting, entitled "Cost of Production and Constructed Value Adjustments for the Preliminary Determination," dated February 12, 2003.

##### 2. Test of Home Market Sales Prices

On a product-specific basis, we compared the adjusted weighted-average COP to the home market sales of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sale prices were below the COP. The prices were adjusted for billing errors and were exclusive of any applicable movement charges, and direct and indirect selling expenses. We recalculated indirect selling expenses for certain sales made through affiliated parties to capture the additional layer of indirect selling expenses incurred by the affiliate. For further discussion, see the memorandum to the File from the Team Re: Calculations Performed for The Nippon Synthetic Chemical Industry Co., Ltd. for the Preliminary Determination in the 2001–2002 Antidumping Duty Investigation of Polyvinyl Alcohol from Japan, dated February 12, 2003, which is available in room B-099 of the Department's CRU. In determining whether to disregard home market sales made at prices less than their COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether such sales were made (1) within an extended period of time in substantial quantities, and (2) at prices which permitted the recovery of all costs within a reasonable period of time.

##### 3. Results of the COP Test

Pursuant to section 773(b)(2)(C), where less than 20 percent of the respondent's sales of a given product are at prices less than the COP, we do not disregard any below-cost sales of that product, because we determine that in such instances the below-cost sales were not made in "substantial quantities." Where 20 percent or more of a respondent's sales of a given product during the POI are at prices less than the

COP, we determine that in such instances the below-cost sales represent "substantial quantities" within an extended period of time, in accordance with section 773(b)(1)(A) of the Act. In such cases, we also determine whether such sales were made at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(1)(B) of the Act.

We found that, for certain specific products, more than 20 percent of Nippon Gohsei's home market sales were at prices less than the COP and, in addition, such sales did not provide for the recovery of costs within a reasonable period of time. We therefore excluded these sales and used the remaining sales, if any, as the basis for determining NV, in accordance with section 773(b)(1) of the Act.

#### D. Level of Trade

In accordance with section 773(a)(1)(B)(i), to the extent practicable, we determine NV based on sales in the comparison market at the same level of trade (LOT) as EP or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). See 19 CFR 412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *Id.*; see also *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa*, 62 FR 61731, 61732 (Nov. 19, 1997). In order to determine whether the comparison sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.*, the "chain of distribution"),<sup>1</sup> including selling functions,<sup>2</sup> class of customer ("customer category"), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying levels of trade for EP and comparison market sales (*i.e.*, NV based on either home market or

third country prices<sup>3</sup>), we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. See *Micron Technology, Inc. v. United States*, Court Nos. 00-1058, -1060 (Fed. Cir. 2001).

When the Department is unable to find sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sale to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it practicable, we make a LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if an NV LOT is more remote from the factory than the CEP LOT and there is no basis for determining whether the difference in LOTs between NV and CEP affected price comparability (*i.e.*, no LOT adjustment was practicable), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. See *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from South Africa*, 62 FR 61731 (Nov. 19, 1997).

We obtained information from Nippon Gohsei regarding the marketing stages involved in making the reported home market and U.S. sales, including a description of the selling activities performed by Nippon Gohsei for each channel of distribution. See page A-11 and exhibit 9 of Nippon Gohsei's November 22 section A response; see also pages 9 through 17 and exhibit 7 of Nippon Gohsei's January 13 response to the Department's supplemental questionnaire.

Nippon Gohsei reported sales through twelve channels of distribution in the home market, including: 1) sales through affiliated distributors to the unaffiliated distributors or end-users; and 2) direct sales to unaffiliated distributors and affiliated and unaffiliated end-users. Nippon Gohsei stated that it performed the following selling functions/services in the home market with respect to these channels of distribution: market research, price negotiations with customers, order processing, interactions with customers, forward inventory maintenance, technical advice, warranty services, freight arrangements, advertising, and

just-in-time delivery. In addition, Nippon Gohsei provided information indicating that its affiliated resellers perform an additional layer of selling functions to customers in the home market.

We first noted that sales by Nippon Gohsei through affiliated distributors pass through two companies before reaching the customer, whereas sales in the other chains of distribution pass directly to the customer. We then examined whether any differences existed with respect to the selling functions performed by Nippon Gohsei in making sales within each of these broad channels of distribution (*i.e.*, through affiliates and direct to the customer). For the sales through Nippon Gohsei's affiliated distributors, we conducted our LOT analysis based on: 1) the selling activities performed by Nippon Gohsei to sell to the affiliated sellers; and 2) the selling activities performed by the affiliated reseller to sell to its unaffiliated customers. The information on the record indicates that the selling functions performed by both Nippon Gohsei and by its affiliated resellers in connection with sales through affiliated resellers are almost identical. Therefore, we find that sales through affiliated parties in the home market constitute one LOT.

Nippon Gohsei also made sales to affiliated and unaffiliated home market end-users and unaffiliated home market distributors. The information on the record also indicates that the selling functions performed in selling directly to end-users and selling to unaffiliated distributors were also substantially the same. Accordingly, we do not find the differences in selling functions so significant as to warrant finding a distinct LOT for sales through these channels. However, when these functions are compared to those for sales through affiliated resellers, we find that Nippon Gohsei and its affiliates provide an additional layer of selling functions that is substantially greater than the selling functions provided for direct sales. Consequently, we preliminarily find that Nippon Gohsei made sales at two LOTs in the home market: 1) sales through affiliated parties, and 2) direct sales to affiliated and unaffiliated customers.

For its sales to the United States, Nippon Gohsei reported two channels of distribution, including sales to unaffiliated trading companies and direct sales to end-users. Nippon Gohsei stated that it performed the following selling functions/services in the U.S. market: market research, price negotiations with customers, order processing, interactions with customers,

<sup>1</sup> The marketing process in the United States and comparison markets begins with the producer and extends to the sale to the final user or consumer. The chain of distribution between the two may have many or few links, and the respondent's sales occur somewhere along this chain. In performing this evaluation, we considered the narrative responses of the respondent to properly determine where in the chain of distribution the sale appears to occur.

<sup>2</sup> Selling functions associated with a particular chain of distribution help us to evaluate the level(s) of trade in a particular market. For purposes of this preliminary determination, we have organized the PVA selling functions into four major categories: sales process and marketing support, freight and delivery, inventory and warehousing, and quality assurance/warranty services, where applicable

<sup>3</sup> Where NV is based on CV, we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, G&A and profit for CV, where possible.

forward inventory maintenance, technical advice, warranty services, freight arrangements, advertising, and just-in-time delivery. The information on the record indicates that the selling functions performed in selling directly to end-users and selling to unaffiliated distributors were also virtually identical. Like Nippon Gohsei's sales to unaffiliated parties in the home market, the differences between the claimed channels in the U.S. market are not substantial enough to warrant a finding of separate LOTs. Therefore, we preliminarily find that Nippon Gohsei made sales through one LOT in the U.S. market: sales to unaffiliated parties. We further preliminarily find that the U.S. LOT is the same as the home market LOT for sales to unaffiliated parties because the selling functions performed by Nippon Gohsei are substantially the same in both markets. Consequently, we compared Nippon Gohsei's EP sales to its sales at the same LOT in the home market. Where we could not compare EP sales to home market sales of the most similar product at the same LOT, we made an LOT adjustment in accordance with section 773(a)(7)(A) of the Act. For further discussion, see the Concurrence Memo.

#### E. Calculation of Normal Value Based on Comparison Market Prices

We calculated NV based on delivered prices to unaffiliated customers or prices to affiliated customers that we

determined to be at arm's-length. Where appropriate, we made adjustments for billing errors. We also made deductions, where appropriate, for movement expenses, including inland freight (plant to distribution warehouse and plant/warehouse to customer) and warehousing under section 773(a)(6)(B)(ii) of the Act. In addition, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for imputed credit expenses and bank charges.

Furthermore, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted home market packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, we made an LOT adjustment under section 773(a)(7)(A) of the Act and 19 CFR 351.412, where appropriate.

#### Currency Conversion

Section 773A(a) of the Act directs the Department to convert foreign currencies based on the U.S. dollar exchange rate in effect on the date of sale of the subject merchandise, except if it is established that a currency transaction on forward markets is directly linked to an export sale. When a company demonstrates that a sale on

forward markets is directly linked to a particular export sale in order to minimize its exposure to exchange rate losses, the Department will use the rate of exchange in the forward currency sale agreement. Accordingly, we made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank, except where Nippon Gohsei demonstrated that its exchange rates were established by forward exchange contracts.

#### Verification

As provided in section 782(i) of the Act, we will verify all information relied upon in making our final determination.

#### Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing the Customs Service to suspend liquidation of all imports of subject merchandise from Japan entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. We will instruct the Customs Service to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the NV exceeds the EP, as indicated in the chart below. These suspension of liquidation instructions will remain in effect until further notice.

The weighted-average dumping margins are as follows:

Exporter/producer	Weighted-average margin (in percent)
Denki Kagaku Kogyo Kabushiki Kaisha .....	144.16
Japan VAM & POVAL Co., Ltd. ....	144.16
Kuraray Co., Ltd. ....	144.16
The Nippon Synthetic Chemical Industry Co., Ltd. ....	24.82
All Others .....	24.82

Pursuant to section 735(c)(5)(A) of the Act, we have excluded from the calculation of the All Others rate margins which are zero or *de minimis*, or determined entirely on facts available. Because we determined the margin for the three non-participating respondents entirely on facts available, we used Nippon Gohsei's margin as the All Others rate.

#### Disclosure

The Department will disclose calculations performed within five days of the date of publication of this notice to the parties in this proceeding in accordance with 19 CFR 351.224(b).

#### ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final antidumping determination is affirmative, the ITC will determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry. The deadline for that ITC determination would be the later of 120 days after the date of this preliminary determination or 45 days after the date of our final determination.

#### Public Comment

Case briefs for this investigation must be submitted no later than seven days after the date of the final verification report issued in this proceeding. Rebuttal briefs must be filed five days

from the deadline date for case briefs. A list of authorities used, a table of contents, and an executive summary of issues should accompany any briefs submitted to the Department. Executive summaries should be limited to five pages total, including footnotes. See 19 CFR 351.309.

Section 774 of the Act provides that the Department will hold a hearing to afford interested parties an opportunity to comment on arguments raised in case briefs, provided that such a hearing is requested by any interested party. If a request for a hearing is made in this investigation, the hearing will tentatively be held two days after the deadline for submission of the rebuttal briefs, at the U.S. Department of Commerce, 14th Street and Constitution



Avenue, NW, Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time. Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request within 10 days of the publication of this notice. Requests should specify the number of participants and provide a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. See 19 CFR 351.310.

We will make our final determination no later than 75 days after the date of this preliminary determination, pursuant to section 735(a)(1) of the Act.

This determination is issued and published pursuant to sections 733(f) and 777(i) of the Act.

Dated: February 12, 2003.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 03-4132 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-DS-S**

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### National Renewable Energy Laboratory; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW, Washington, DC.

*Docket Number:* 02-051.

*Applicant:* National Renewable Energy Laboratory, Golden, CO 80401.

*Instrument:* Ignition Quality Tester.

*Manufacturer:* Advanced Engine Technology Ltd., United Kingdom.

*Intended Use:* See notice at 68 FR 742, January 7, 2003.

*Comments:* None received.

*Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

*Reasons:* The foreign instrument provides standardized measurements of ignition delay, maximum chamber temperature, heat rise and autoignition temperature for diesel and alternative fuel and additive compounds. The U.S. Department of Agriculture and

Southwest Research Institute advised February 4, 2003 that (1) this capability is pertinent to the applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

**Gerald A. Zerdy,**

*Program Manager, Statutory Import Programs Staff.*

[FR Doc. 03-4133 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Applications for Duty-Free Entry of Scientific Instruments

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

*Docket Number:* 03-004.

*Applicant:* University of Kentucky, Chem/Physics Building, Room 177, Lexington, KY 40506.

*Instrument:* IR Image Furnace, Model SCII-MDH-11020.

*Manufacturer:* NEC Machinery Corporation, Japan.

*Intended Use:* The instrument is intended to be used for synthesis of single crystals of oxides such as ruthenium and copper for fundamental materials research and to understand their magnetic and electronic properties.

*Application accepted by Commissioner of Customs:* January 24, 2003.

*Docket Number:* 03-005.

*Applicant:* Northwestern University, Searle 5-474, MC S205, 320 East Superior Street, Chicago, IL 60637.

*Instrument:* MSM System Series 300 Yeast Manipulator and Micro Zapper.

*Manufacturer:* Singer Instrument Company Limited, United Kingdom.

*Intended Use:* The instrument is intended to be used to study the biological function of yeast SWI/SNF chromatin remodeling complex. Experiments to be conducted include yeast mating, sporulation and zygote isolation.

*Application accepted by Commissioner of Customs:* January 30, 2003.

*Docket Number:* 03-006.

*Applicant:* MetroHealth Medical Center, 2500 MetroHealth Drive, Cleveland, OH 44109-1998.

*Instrument:* Electron Microscope, Model Tecnai G<sub>2</sub> 12 TWIN.

*Manufacturer:* FEI Company, The Netherlands.

*Intended Use:* The instrument is intended to be used for research which will include:

1. Structural alterations in pulmonary vasculature caused by embolized particles present in pharmaceutical tablets.

2. Structural-correlative studies of lung morphology in patients with acute lung injury, including adult respiratory distress syndrome.

3. Evaluation of ultrastructural abnormalities of human and animal neoplasms including pulmonary and extrapulmonary tumors.

4. Defining new ultrastructural abnormalities of respiratory cilia which may play a role in "immotile cilia syndrome" and the development of bronchiectasis.

5. Response of the human lung to mineral dusts.

6. Defining gene function in disease pathogenesis.

7. Determining which neurotransmitter peptides are localized in DiO-labelled synaptic terminals of the aortic depressor nerve.

*Application accepted by Commissioner of Customs:* February 4, 2003.

**Gerald A. Zerdy,**

*Program Manager, Statutory Import Programs Staff.*

[FR Doc. 03-4134 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-DS-P**



**DEPARTMENT OF COMMERCE****National Institute of Standards and Technology****[Docket No.: 030123017-3017-01]****RIN: 0693-ZA50****Small Grants Programs; Availability of Funds****AGENCY:** National Institute of Standards and Technology, Commerce.**ACTION:** Notice.

**SUMMARY:** The National Institute of Standards and Technology (NIST) announces that the following programs are soliciting applications for financial assistance for FY 2003: (1) The Precision Measurement Grants Program; (2) the 2003 Summer Undergraduate Research Fellowships (SURF) in the areas of Electronics and Electrical Engineering, Manufacturing Engineering, Chemical Science and Technology, Physics, Materials Science and Engineering, Building and Fire Research, and Information Technology; (3) the Electronics and Electrical Engineering Laboratory Grants Program; (4) the Manufacturing Engineering Laboratory Grants Program; (5) the Chemical Science and Technology Laboratory Grants Program; (6) the Physics Laboratory Grants Program; (7) the Materials Science and Engineering Laboratory Grants Program; (8) the Building Research Grants and Cooperative Agreements Program; and (9) the Fire Research Grants Program.

The Precision Measurement Grants Program is seeking proposals for significant, primarily experimental, research in the field of fundamental measurement or the determination of fundamental constants.

The programs "SURFing the Electronics and Electrical Engineering Laboratory," "SURFing the Manufacturing Engineering Laboratory," "SURFing the Chemical Science and Technology Laboratory," "SURFing the Physics Laboratory," "SURFing the Materials Science and Engineering Laboratory," "SURFing the Building and Fire Research Laboratory," and "SURFing the Information Technology Laboratory," will provide an opportunity for the NIST Electronics and Electrical Engineering Laboratory (EEEL), Manufacturing Engineering Laboratory (MEL), Chemical Science and Technology Laboratory (CSTL) Physics Laboratory (PL), Materials Science and Engineering Laboratory (MSEL), Building and Fire Research Laboratory (BFRL), and Information Technology Laboratory (ITL), and the

National Science Foundation (NSF) to join in a partnership to encourage outstanding undergraduate students to pursue careers in science and engineering.

The EEEL program will provide research opportunities with internationally known NIST scientists in the fields of semiconductors (including mainstream silicon, power devices, and compound semiconductors), fundamental electrical measurements, electronic instrumentation, electrical systems, and electronic information. The MEL program will provide research opportunities with internationally known NIST scientists in the fields of intelligent systems, manufacturing metrology, precision engineering, and manufacturing systems integration. The CSTL program will provide research opportunities with internationally known NIST scientists in the fields of chemical characterization of materials, process metrology, chemical and biochemical sensing, nanotechnology, healthcare measurements, environmental measurements, microelectronics, physical property data, chemical and biochemical data, bio-molecules and materials, DNA technologies, and international measurement standards. The PL program will involve students in world-class atomic, molecular, optical (AMO) and radiation physics research with internationally known physicists in the NIST Physics Laboratory. The MSEL program will provide research opportunities with internationally known NIST scientists in the fields of ceramics, solid state chemistry, metallurgy, polymers, neutron condensed matter science, and materials reliability. The BFRL program will provide research opportunities with internationally known NIST scientists in the fields of building materials (concrete, coating), structure (earthquake), building environment (indoor air quality, thermal machinery), and fire science and engineering. The ITL program will provide research opportunities with internationally known NIST scientists in the fields of networking, software quality, security, information access, convergent systems, mathematical science, and statistics. The NIST Program Directors will work with physics, chemistry, materials science, manufacturing engineering, intelligent systems, automated production, precision engineering, information technology, building materials, constructed structures, and other science-related department chairs and directors of multi-disciplinary

academic organizations to identify outstanding undergraduates (including graduating seniors) who would benefit from off-campus summer research in an honors academy environment.

The Electronics and Electrical Engineering Laboratory (EEEL) Grants Program provides grants and cooperative agreements for the development of fundamental electrical metrology and of metrology supporting industry and government agencies in the broad areas of semiconductors, electronic instrumentation, radio-frequency technology, optoelectronics, magnetics, video, electronic commerce as applied to electronic products and devices, the transmission and distribution of electrical power, national electrical standards (fundamental, generally quantum-based physical standards), and law enforcement standards.

The Manufacturing Engineering Laboratory (MEL) Grants Program will provide grants and cooperative agreements in the following fields of research: Dimensional Metrology for Manufacturing, Mechanical Metrology for Manufacturing, Intelligent Systems, and Information Systems Integration for Applications in Manufacturing.

The Chemical Science and Technology Laboratory (CSTL) Grants Program will provide grants and cooperative agreements in the following fields of measurement science research, focused on reference methods, reference materials and reference data: Biotechnology, Process Measurements, Surface and Microanalysis Science, Physical and Chemical Properties, and Analytical Chemistry.

The Physics Laboratory (PL) Grants Program will provide grants and cooperative agreements in the following fields of research: Electron and Optical Physics, Atomic Physics, Optical Technology, Ionizing Radiation, and Time and Frequency.

The Materials Science and Engineering Laboratory (MSEL) Grants Program will provide grants and cooperative agreements in the following fields of research: Ceramics, Metallurgy, Polymer Sciences, Neutron Scattering Research and Spectroscopy.

The Building Research Grants and Cooperative Agreements Program will provide grants and cooperative agreements in the following fields of research: Structures, Construction Metrology and Automation, Inorganic Materials, Polymeric Materials, Thermal Machinery, Mechanical Systems and Controls, Heat Transfer and Alternative Energy Systems, Computer Integrated Construction, Indoor Air Quality and Ventilation.

The Fire Research Grants Program will provide funding for innovative ideas in the fire research area generated by the proposal writer, who chooses the topic and approach, consistent with the program description and objectives of this notice.

#### SUPPLEMENTARY INFORMATION:

##### Precision Measurement Grants Program

**Dates:** Applicants for the Precision Measurement Grants Program must submit an abbreviated proposal for preliminary screening. Based on the merit of the abbreviated proposal, applicants will be advised whether a full proposal should be submitted. The abbreviated proposals must be received at the address listed below no later than 5 p.m. eastern standard time on March 24, 2003. Proposals received after this deadline will be returned with no further consideration. Finalists will be selected by approximately May 9, 2003, and will be requested to submit full proposals to NIST by close of business on June 20, 2003. NIST expects to issue awards on or before September 30, 2003.

**Addresses:** For the Precision Measurement Grants Program, applicants are requested to direct technical questions and submit an abbreviated proposal (original and two signed copies), with a description of their proposed work of no more than five double spaced pages to: Dr. Peter J. Mohr, Manager, NIST Precision Measurement Grants Program, National Institute of Standards and Technology, Bldg. 225, Rm. B161, 100 Bureau Drive, Stop 8401, Gaithersburg, MD 20899-8401. Tel: (301) 975-3217. E-mail: [mohr@nist.gov](mailto:mohr@nist.gov). Web site: <http://physics.nist.gov/pmg>.

Although applicants are not required to submit more than three copies of the proposal, the normal review process for the Precision Measurement Grants Program utilizes 10 copies. Applicants are encouraged to submit sufficient proposal copies for the full review process if they wish all reviewers to receive color, unusually sized (not 8.5" x 11"), or otherwise unusual materials submitted as part of the proposal. Only three copies of the Federally required forms are needed.

**Authority:** The authority for the Precision Measurement Grants Program is as follows: As authorized by 15 U.S.C. 272 (b) and (c), NIST conducts directly, and supports through grants and cooperative agreements, a basic and applied research program in the general area of fundamental measurement and the determination of fundamental constants of nature.

**Program Description and Objectives:** The program description and objectives for the Precision Measurement Grants

Program are as follows: as part of its research program, since 1970 NIST has awarded Precision Measurement Grants primarily to universities and colleges so that faculty may conduct significant, primarily experimental research in the field of fundamental measurement or the determination of fundamental constants. NIST sponsors these grants and cooperative agreements primarily to encourage basic, measurement-related research in universities and colleges and other research laboratories and to foster contacts between NIST scientists and those faculty members of academic institutions and other researchers who are actively engaged in such work. The Precision Measurement Grants are also intended to make it possible for researchers to pursue new, fundamental measurement ideas for which other sources of support may be difficult to find. There is some latitude in research topics that will be considered under the Precision Measurement Grants Program. The key requirement is that the proposed project support NIST's ongoing work in the field of basic measurement science, which includes:

1. Experimental and theoretical studies of fundamental physical phenomena which test the basic laws of physics or which may lead to new or improved fundamental measurement methods and standards.

2. The determination of important fundamental physical constants.

Although proposals for either experimental or theoretical research will be considered, the former will be given preference because of the more immediate applicability of experimental work to metrology. Proposals from workers at the assistant and associate professor level who have some record of accomplishment are especially encouraged in view of the comparative difficulty researchers have in obtaining funds at the early stages of their careers.

Typical projects which have been funded through the NIST Precision Measurement Grants Program include:

- (1) Precision optical spectroscopy of positronium, S. Chu, Stanford University.

- (2) Spectroscopy of francium: towards a precise parity nonconservation measurement in a laser trap, L. A. Orozco, State University of New York at Stony Brook.

- (3) Measurement of Newton's constant G using a new method, J.H. Gundlach, University of Washington.

- (4) Measurement of the polarization of the cosmic microwave background, S.T. Staggs, Princeton University.

- (5) Combining the quantum Hall and AC Josephson effects for electric current

metrology, E.A. Gwinn, University of California, Santa Barbara.

- (6) A test of CPT symmetry using a new K-3He self-compensating magnetometer, M.V. Romalis, University of Washington.

**Eligibility:** Eligible applicants are institutions of higher education, other non-profits, commercial organizations, international organizations, State, local and Indian tribal governments and Federal agencies with appropriate legal authority.

##### *Award Period and Funding*

**Availability:** Applicants should propose multi-year projects for up to three years at no more than \$50,000 per year. NIST anticipates spending \$100,000 this year for two new grants at \$50,000 each for the first year of the research projects. NIST may award all, none or some of these new awards. Second and third year funding will be at the discretion of NIST, based on satisfactory performance, continuing relevance to program objectives, and the availability of funds.

**Proposal Review Process:** For the Precision Measurement Grants Program, to simplify the proposal writing and evaluation process, the following selection procedure will be used:

Applicants will initially submit abbreviated proposals, containing a description of the proposed project, including sufficient information to address the evaluation criteria, with a total length of no more than five double spaced pages, to the mailing address given above in the *Addresses* section. These proposals will be screened to determine whether they address the requirements outlined in this notice. Proposals that do not meet those requirements will not be considered further. Eight independent, objective individuals, at least half of whom are NIST employees, and who are knowledgeable about the scientific areas that the program addresses will conduct a technical review of each proposal, based on the evaluation criteria described in the Evaluation Criteria section for this program. The proposals will then be ranked based on the average of the reviewers' rankings. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but ranks will be determined on an individual basis, not as a consensus.

The Precision Measurement Grants Program manager, the selecting official, will then select approximately four to eight finalists. In selecting finalists, the selecting official will take into consideration the results of the reviewers' evaluations, including rank,

and relevance to the program objectives described above.

Finalists will then be asked to submit full proposals containing a description of the proposed project, including sufficient information to address the evaluation criteria, with a length of no more than ten (10) double spaced pages in addition to the federally mandated forms and certifications, to the mailing address given above in the **ADDRESSES** section. The same independent reviewers will then evaluate the detailed proposals based on the same evaluation criteria, and the proposals will be ranked as previously described. In selecting proposals that will be recommended for funding, the selecting official will take into consideration the results of the reviewers' evaluations, including rank, and relevance to the program objectives described in the Program Description and Objectives section for this program.

The final approval of selected applications and award of grants or cooperative agreements will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible.

Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award.

The decision of the Grants Officer is final.

**Evaluation Criteria:** The evaluation criteria to be used in evaluating the abbreviated application proposals and full proposals are:

1. *The importance of the proposed research*—Does it have the potential of answering some currently pressing question or of opening up a whole new area of activity?

2. *The relationship of the proposed research to NIST's ongoing work*—Will it support one of NIST's current efforts to develop a new or improved fundamental measurement method or physical standard, test the basic laws of physics, or provide an improved value for a fundamental constant?

3. *The feasibility of the research and the potential impact of the grant*—Is it likely that significant progress can be made in a three year time period with the funds and personnel available and that the funding will enable work that would otherwise not be done with existing or potential funding?

4. *The qualifications of the applicant*—Does the educational and employment background and the quality of the research, based on recent publications, of the applicant indicate that there is a high probability that the proposed research will be carried out successfully?

Each of these factors is given equal weight in the evaluation process.

**Matching Requirements:** The Precision Measurement Grants Program does not require any matching funds.

**Application Kit:** For the Precision Measurement Grants Program, an application kit, containing all required application forms and certifications will be provided to the finalists by Ms. Bonnie Whipp, (301) 975-4750.

#### **EEEL, MEL, CSTL, PL, MSEL, BFRL, and ITL SURF Programs**

**Dates:** All SURF Program proposals must be received no later than the close of business March 24, 2003.

**Addresses:** For all SURF Programs, applicant institutions must submit one signed original and two copies of the proposal to: Attn.: Ms. Anita Sweigert, Administrative Coordinator, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8400, Gaithersburg, MD 20899-8400. Tel: (301) 975-4200. E-mail: [anita.sweigert@nist.gov](mailto:anita.sweigert@nist.gov). Web site: <http://www.surf.nist.gov/surf2.htm>.

Technical questions for the programs should be directed to the following contact persons: For the EEEL SURF Program, Dr. David Newell, Tel: (301) 975-4228, E-mail:

[david.newell@nist.gov](mailto:david.newell@nist.gov); for the MEL SURF Program, Ms. Lisa Jean Fronczek, Tel: (301) 975-6633, E-mail:

[lfronczek@nist.gov](mailto:lfronczek@nist.gov); for the CSTL SURF Program, Dr. Albert Lee, Tel: (301) 975-2857, E-mail: [albert.lee@nist.gov](mailto:albert.lee@nist.gov) or Jeanice Brown Thomas, Tel: (301) 975-3120, E-mail:

[jeanice.brownthomas@nist.gov](mailto:jeanice.brownthomas@nist.gov); for the PL SURF Program, Dr. Marc Desrosiers, Tel: (301) 975-5639, E-mail:

[marc.desrosiers@nist.gov](mailto:marc.desrosiers@nist.gov); for the MSEL SURF Program, Dr. Terrell A. Vanderah, Tel: (301) 975-5785, E-mail:

[terrell.vanderah@nist.gov](mailto:terrell.vanderah@nist.gov); for the BFRL SURF Program, Dr. Chris White, Tel: (301) 975-6016, E-mail:

[cwhite@nist.gov](mailto:cwhite@nist.gov), or Dr. Chiara Ferraris, Tel: (301) 975-6711, E-mail:

[chiara.ferraris@nist.gov](mailto:chiara.ferraris@nist.gov); and for the ITL SURF Program, Dr. Larry Reeker, Tel: (301) 975-5147, E-mail:

[larry.reeker@nist.gov](mailto:larry.reeker@nist.gov).

**Authority:** The authority for the SURF Programs is as follows: 15 U.S.C. 278g-1 authorizes NIST to fund financial assistance awards to students at institutions of higher learning within the United States. These

students must show promise as present or future contributors to the missions of NIST. Cooperative agreements are awarded to assure continued growth and progress of science and engineering in the United States, including the encouragement of women and minority students to continue their professional development.

**Program Description and Objectives:** The objective of the SURF Programs is to build a mutually beneficial relationship between the student, the institution of higher learning, and NIST.

The program description for the SURF Programs is as follows: NIST is one of the nation's premiere research institutions for the physical and engineering sciences and, as the lead Federal agency for technology transfer, it provides a strong interface between government, industry and academia. NIST embodies a special science culture, developed from a large and well-equipped research staff that enthusiastically blends programs that address the immediate needs of industry with longer-term research that anticipates future needs. This occurs in few other places and enables the EEEL, MEL, CSTL, PL, MSEL, BFRL, and ITL to offer unique research and training opportunities for undergraduates, providing them a research-rich environment and exposure to state of the art equipment.

NIST's EEEL strives to be the world's best source of fundamental and industrial-reference measurement methods and physical standards for electrotechnology. To be a world-class resource for semiconductor measurements, data, models, and standards focused on enhancing U.S. technological competitiveness in the world market, research is conducted in semiconductor materials, processing, devices, and integrated circuits to provide, through both experimental and theoretical work, the necessary basis for understanding measurement-related requirements in semiconductor technology. To provide the world's most technically advanced and fundamentally sound basis for all electrical measurements in the United States, the EEEL's research projects include maintaining and disseminating the national electrical standards, developing the measurement methods and services needed to support electrical materials, components, instruments, and systems used for the generation, transmission, and application of conducted electrical power, and related activities in support of the electronics industry including research on video technology and electronic product data exchange.

NIST's MEL conducts theoretical and experimental research in length, mass, force, vibration, acoustics, and ultrasonics, as well as intelligent machines, precision control of machine tools, and information technology for the integration of all elements of a product's life cycle. Much of this applied research is devoted to overcoming barriers to the next technological revolution, in which manufacturing facilities are spread across the globe. MEL's research and development leads to standards, test methods and data that are crucial to industry's success in exploiting advanced manufacturing technology. Critical components of manufacturing at any level are measurement and measurement-related standards, not just of products, but increasingly of information about products and processes. Thus, MEL programs enhance both physical and information-based measurements and standards. Research projects can be theoretical or experimental, and will range in focus from intelligent machine control, characterizing a manufacturing process or improving product data exchange in manufacturing and related industries such as healthcare, to the accurate measurement of an artifact's dimensions.

NIST's CSTL strives to be a world-class research laboratory that is recognized by the nation as the primary source for the chemical, biochemical, and chemical engineering measurements, data, models, and reference standards that are required to enhance U.S. industrial competitiveness in the world market. CSTL is the primary reference laboratory for chemical measurements, entrusted with developing, maintaining, advancing, and enabling the chemical measurement system for the United States of America, thereby enhancing industry's productivity and competitiveness, establishing comparability of measurements to facilitate equity of global trade, and improving public health, safety, and environmental quality. CSTL's activities include: Transportation, Biomaterials, Biotechnology, Chemical and Allied Products, Energy Systems, Environmental Technology and Systems, Health and Medical Products and Services, Industrial and Analytical Instruments and Services, Forensics, Microelectronics, Food and Nutritional Products, International Measurement Standards, Data and Informatics, and emerging Technologies (Nanotechnology, Molecular

Electronics, Microfluidics, Combinatorial Chemistry).

Attending to the long-term needs of many U.S. high-technology industries, NIST's PL conducts basic research in the areas of quantum, electron, optical, atomic, molecular, and radiation physics. To achieve these goals, PL staff develop and utilize highly specialized equipment, such as polarized electron microscopes, scanning tunneling microscopes, lasers, and x-ray and synchrotron radiation sources. Research projects can be theoretical or experimental and will range in focus from computer modeling of fundamental processes through trapping atoms and choreographing molecular collisions, to standards for radiation therapy.

NIST's MSEL conducts basic research in the electronic, magnetic, optical, superconducting, mechanical, thermal, chemical, and structural properties of metals, ceramics, polymers, and composites. Much of this applied research is devoted to overcoming barriers to the next technological revolution, in which individual atoms and molecules will serve as the fundamental building blocks of devices. Preparation of unique materials by atomic level tailoring of multi-layers, perfect single crystals, and nanocomposites are just some of the future technologies being developed and explored in NIST's MSEL. To achieve these goals, staff develop and utilize highly specialized equipment, such as high resolution electron microscopes, atomic force microscopes, neutron scattering instruments, x-ray diffraction sources, lasers, magnetometers, plasma furnaces, melt spinners, molecular beam epitaxy systems, and thermal spray systems. Research projects can be theoretical or experimental and will range in focus from the structural, chemical, and morphological characterization of advanced materials made in the NIST laboratories to the accurate measurement of the unique properties possessed by these special materials.

NIST's BFRL provides technical leadership and participates in developing the measurement and standards infrastructure related to materials critical to U.S. industry, academia, government, and the public. Building and Fire Research programs at NIST cover a full range of materials issues from design to processing to performance. Separate research initiatives address concrete, coating, earthquake resistance of structures, fire science and engineering, the theory and modeling of materials, and materials reliability. Through laboratory-

organized consortia and one-on-one collaborations, BFRL's scientists and engineers work closely with industrial researchers, manufacturers of high-technology products, and the major users of advanced materials.

NIST's ITL responds to industry and user needs for objective, neutral tests for information technology. These are enabling tools that help companies produce the next generation of products and services, and that help industries and individuals use these complex products and services. ITL works with industry, research and government organizations to develop and demonstrate tests, test methods, reference data, proof of concept implementations and other infrastructural technologies. Program activities include: high performance computing and communications systems; emerging network technologies; access to, exchange, and retrieval of complex information; computational and statistical methods; information security; and testing tools and methods to improve the quality of software.

SURF students will have the opportunity to work one-on-one with our nation's top scientists and engineers. It is anticipated that successful SURF students will move from a position of reliance on guidance from their research advisors to one of research independence during the twelve-week period. One goal of this partnership is to provide opportunities for our nation's next generation of scientists and engineers to engage in world-class scientific research at NIST, especially in ground-breaking areas of emerging technologies. This carries with it the hope of motivating individuals to pursue a Ph.D. in physics, chemistry, materials science, engineering, mathematics, or computer science, and to consider research careers. The SURF Programs will help to forge partnerships with NSF and with post-secondary institutions that demonstrate strong, hands-on undergraduate science curricula, especially those with a demonstrated commitment to the education of women, minorities, and students with disabilities.

**Eligibility:** The EEEL, MEL, CSTL, PL, MSEL, BFRL, and ITL, SURF Programs are open to colleges and universities in the United States and its territories with degree granting programs in materials science, chemistry, engineering, computer science, mathematics, or physics. Participating students must be U.S. citizens or permanent U.S. residents.

**Funding Availability:** Funds budgeted for payment to students under these

programs are stipends, not salary. The SURF Programs will not authorize funds for indirect costs or fringe benefits.

For the EEEL SURF Program, the NIST EEEL anticipates receiving funding as a NSF REU Program at the level of \$73,000 per year. It is anticipated that the funding for the EEEL SURF Program will provide for the costs of stipends, travel and lodging, and the conference attendance for approximately eleven students.

For the MEL SURF Program, the NIST MEL anticipates receiving funding as a NSF REU Program at the level of \$52,000 per year. For the CSTL SURF Program, the NIST CSTL will pursue funding as a NSF REU Program at the level of \$40,000 per year and may contribute additional NIST CSTL funds to support additional students. For the BFRL SURF Program, the NIST BFRL anticipates receiving funding as a NSF REU Program at the level of \$50,000 per year. For the ITL SURF Program, the NIST ITL anticipates receiving funding as a NSF REU Program at the level of \$50,000 per year. It is anticipated that the funding for the MEL, CSTL, BFRL and ITL SURF Programs will provide for the costs of stipends, travel and lodging, and the conference attendance of eight students for each program.

For the PL SURF Program, the NIST PL will commit approximately \$50,000 to support these cooperative agreements. The NIST PL's REU Program is anticipating renewal of funding by the NSF at the level of \$85,000 per year. The anticipated direct costs for stipends, travel, lodging, and conference attendance for 22 students is about \$135,000.

For the MSEL SURF Program, the NIST MSEL anticipates receiving funding as a NSF REU Program at the level of \$70,000 per year. It is anticipated that this funding will provide for the costs of stipends, travel and lodging, and the conference attendance of 10 students.

The actual number of awards made under this announcement will depend on the actual costs. For all SURF Programs described in this notice, it is expected that individual awards to institutions will range from approximately \$3,000 to \$70,000. NIST is in the process of determining whether NIST will contract directly with apartment complexes for student housing, or whether funding for student housing will be included in cooperative agreements awarded as a result of this notice. Selected applicants will be informed prior to award whether housing will be provided via the cooperative agreement or provided separately by NIST.

*Proposal Review Process:* All SURF Program proposals are submitted to the Administrative Coordinator. Each proposal is examined for completeness and responsiveness. Substantially incomplete or non-responsive proposals will not be considered for funding, and the applicant will be notified. The Program will retain one copy of each non-responsive application for three years for record keeping purposes. The remaining copies will be destroyed. Proposals should include the following:

- (A) Student Information:
  - (1) Student application information cover sheet;
  - (2) Academic transcript for each student nominated for participation (students must have a recommended G.P.A. of 3.0 or better, out of a possible 4.0);
  - (3) A personal statement from each student and statement of commitment to participate in the 2003 SURF program, including a description of the student's prioritized research interests;
  - (4) A resume for each student;
  - (5) Two letters of recommendation for each student;
  - (6) Verification of U.S. citizenship or permanent legal resident status for each student; and
  - (7) Verification of health coverage for each student.

(B) Information About the Applicant Institution:

- (1) Description of the institution's education and research programs; and
- (2) A summary list of the student(s) being nominated.

Institution proposals will be separated into student/institution packets. Each student/institution packet will be comprised of the required application forms, including a complete copy of the student information and a complete copy of the institution information. The student/institution packets will be directed to the SURF Program designated by the student as his/her first choice. Each SURF Program will have three independent, objective NIST employees who are knowledgeable in the scientific areas that the program addresses conduct a technical review of each student/institution packet based on the Evaluation Criteria for the SURF Programs described in this notice. Each technical reviewer will recommend that each student/institution packet be placed into one of three categories: Priority funding; fund if possible; and do not fund. Each student/institution packet will then be placed into one of the three categories by the Program's Director, who will take into consideration the reviewers' recommendations, the relevance of the student's course of study to the program

objectives of the NIST laboratory in which that SURF Program resides as described in the Program Description and Objectives section of this notice, the relevance of the student's statement of commitment to the goals of the SURF Program, and the availability of funding.

Student/institution packets placed in the priority funding category will be selected for funding in that SURF Program. Student/institution packets placed in the do not fund category will not be considered for funding.

Student/institution packets placed in the Fund if Possible Category will be considered for funding by the SURF Program designated by the student as his/her second choice. In making selections for funding, the Director of the student's second choice SURF Program will take into consideration the recommendations of the reviewers who conducted the technical reviews for the student's first choice SURF Program, the program objectives of the NIST laboratory in which the student's second choice SURF Program resides as described in the Program Description and Objectives section of this notice, the relevance of the student's statement of commitment to the goals of the SURF Program, and the availability of funding.

Students not selected for funding by their first or second choice SURF Program, and students who did not designate a second choice, will then be considered for funding from all SURF Programs that still have slots available. In making selections for funding, the SURF Program Directors will take into consideration the recommendations of the reviewers who conducted the technical reviews for the student's first choice SURF Program, the program objectives of the NIST laboratory in which their SURF Program resides as described in the Program Description and Objectives section of this notice, the relevance to the goals of the SURF Program, and the availability of funding.

Student/institution packets placed in the fund if possible category, but not selected through the process described above, will not be funded.

The final approval of selected applications and award of cooperative agreements will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by

the agency prior to award. The decision of the Grants Officer is final.

**Evaluation Criteria:** For the SURF Programs, the evaluation criteria are:

Evaluation of student's academic ability and commitment to program goals: includes evaluation of the following: completed course work; expressed research interest; compatibility of the expressed research interest with SURF Program research areas; research skills; grade point average in courses relevant to the SURF Program; career goals; honors and activities.

Evaluation of applicant institution's commitment to program goals: includes evaluation of the following: the institution's academic department(s) relevant to the discipline(s) of the student(s).

Each of these factors is given equal weight in the evaluation process.

**Award Period:** The SURF Programs are anticipated to run from May 27 through August 15, 2003; adjustments may be made to accommodate specific academic schedules (e.g., a limited number of 9-week cooperative agreements).

**Matching Requirements:** The SURF Programs do not require any matching funds.

**Application Kit:** For the EEEL, MEL, CSTL, PL, MSEL, BFRL, and ITL SURF Programs, an application kit, containing all required forms and certifications, may be obtained by contacting Ms. Anita Sweigert, (301) 975-4200; websites for each program's application kit may be accessed through the following Web site: <http://www.surf.nist.gov/surf2.htm>.

### **Electronics and Electrical Engineering Laboratory (EEEL) Grants Program**

**Dates:** The Electronics and Electrical Engineering Laboratory Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds.

**Addresses:** For the Electronics and Electrical Engineering Laboratory Grants Program, submit one signed original and two copies of the proposal package to: Electronics and Electrical Engineering Laboratory, Attn.: Sheila Bryner, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8100, Gaithersburg, MD 20899-8100. Tel.: (301) 975-2220. Fax: (301) 975-4091.

**Authority:** As authorized by 15 U.S.C. 272(b) and (c), the NIST Electronics and Electrical Engineering Laboratory conducts a

basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** The Electronics and Electrical Engineering Laboratory Grants Program solicits proposals in support of the broad program objectives identified below.

The Electronics and Electrical Engineering Laboratory Grants Program supports the formal mission of the Electronics and Electrical Engineering Laboratory, which is to strengthen the U.S. economy and improve the quality of life by providing measurement science and technology, and by advancing standards, primarily for the electronics and electrical industries.

More specifically, the Electronics and Electrical Engineering Laboratory Grants Program solicits proposals to support specific programs in the areas of metrology for semiconductors (including mainstream silicon, power devices, and compound semiconductors), superconductors (including cryoelectronics and bulk superconductors), electronic instrumentation, optoelectronics, magnetics (including bulk magnetic materials and magnetic data storage), video (including flat-panel displays), electronic commerce as applied to electronic products and devices, the transmission and distribution of electrical power, national electrical standards (fundamental, generally quantum-based physical standards), and law enforcement (clothing, communication systems, emergency equipment, investigative aids, protective equipment, security systems, vehicles, speed-measuring equipment, weapons, and analytical techniques and standard reference materials used by the public safety community).

For details on these various activities, please see the Electronics and Electrical Engineering Laboratory Web site at <http://www.eeel.nist.gov>. Note that documents describing the current programs for the five participating technical divisions and two offices are available through the home page.

Technical contacts for these areas are:

#### **Semiconductors**

**Semiconductor Electronics Division—**Division Chief: Dr. David G. Seiler; (301) 975-2054; [david.seiler@nist.gov](mailto:david.seiler@nist.gov).

**Office of Microelectronics Programs—**Director: Dr. Stephen Knight; (301) 975-4400; [stephen.knight@nist.gov](mailto:stephen.knight@nist.gov).

#### **Superconductors (Bulk); Magnetics**

**Magnetic Technology Division—**Division Chief: Dr. Alan F. Clark; (303) 497-5477; [aclark@boulder.nist.gov](mailto:aclark@boulder.nist.gov).

**Superconductors (Cryoelectronics); National Electrical Standards (Josephson Array Development)**

**Electromagnetic Technology Division—**Division Chief: Dr. Richard E. Harris; (303) 497-3678; [richard.harris@boulder.nist.gov](mailto:richard.harris@boulder.nist.gov).

**Electronic Instrumentation; Video; Electronic Commerce; National Electrical Standards (Other Than Josephson Array Development)**

**Electricity Division—**Division Chief: Dr. James K. Olthoff; (301) 975-2400; [james.olthoff@nist.gov](mailto:james.olthoff@nist.gov).

#### **Optoelectronics**

**Optoelectronics Division; Office of Optoelectronics Programs—**Division Chief and Office Director: Dr. Gordon W. Day; (303) 497-5432; [gwday@boulder.nist.gov](mailto:gwday@boulder.nist.gov).

#### **Law enforcement**

**Office of Law Enforcement Standards—**Director: Dr. Kathleen Higgins; (301) 975-2757; [kathleen.higgins@nist.gov](mailto:kathleen.higgins@nist.gov).

**Eligibility:** The Electronics and Electrical Engineering Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** Over the past three years, the Electronics and Electrical Engineering laboratory funded a total of approximately \$1,500,000 in grants and cooperative agreements. The amount available each year fluctuates considerably based on programmatic needs. Individual awards are expected to range between \$5,000 and \$150,000.

**Proposal Review Process:** For the Electronics and Electrical Engineering Laboratory Grants Program, proposals will be distributed to the appropriate Division Chief or Office Director or designee based on technical area by one or more technical professionals familiar with the programs of the Electronics and Electrical Engineering Laboratory. The proposals will be reviewed in a two-step process. First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the Program Description and Objectives section above that the proposal addresses will conduct a technical review of each

proposal, based on the evaluation criteria described below.

Reviews will be conducted on a quarterly basis, and all proposals received during the quarter will be ranked based on the reviewers' scores. Second, the Division Chief or Office Director will make application selections. In making application selections, the Division Chief or Office Director will take into consideration the results of the reviewers' evaluations, the compatibility of the applicant's proposal with the program objectives of the particular division or office that the proposal addresses, the availability of funding, and relevance to the objectives of the Electronics and Electrical Engineering Laboratory Grants Program, as described above. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final. Applicants should allow up to 90 days processing time.

**Evaluation Criteria:** For the Electronics and Electrical Engineering Laboratory Grants Program, the evaluation criteria and weights to be used by the technical reviewers in evaluating the proposals are as follows:

Proposal addresses specific program objectives as described in this notice (25%);

Proposal provides evidence of applicant's expertise in relevant technical area (20%);

Proposal offers innovative approach (20%);

Proposal provides realistic schedule with defined milestones (20%);

Proposal provides adequate rationale for budget (15%).

**Award Period:** For the Electronics and Electrical Engineering Laboratory Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase

funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Electronics and Electrical Engineering Laboratory Grants Program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (i.e., the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

**Matching Requirements:** The Electronics and Electrical Engineering Laboratory Grants Program does not require any matching funds.

**Application Kit:** An application kit, containing all required application forms and certifications is available on the web at <http://www.eeel.nist.gov/eeel/grants/> or by contacting: Sheilda Bryner, (301) 975-2220, [sheilda.bryner@nist.gov](mailto:sheilda.bryner@nist.gov).

#### **Manufacturing Engineering Laboratory (MEL) Grants Program**

**Dates:** The MEL Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds. Each applicant must submit one signed original and two copies of each proposal along with a Grant Application (Standard Form 424 REV. 7/97 and other required forms).

**Addresses:** For the MEL Grants Program, submit one signed original and two copies of the proposal, clearly marked to identify the field of research, to: Manufacturing Engineering Laboratory, Attn: Mrs. Barbara Horner, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8200, Building 220, Room B322, Gaithersburg, Maryland 20899-8200. Tel: (301) 975-4345. E-mail: [barbara.horner@nist.gov](mailto:barbara.horner@nist.gov).

**Authority:** As authorized under 15 U.S.C. 272(b) and (c), the MEL conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** All proposals submitted must be in accordance with the program objectives listed below. The appropriate Program Manager for each field of research may be contacted for clarification of the program objectives.

**I. Precision Engineering Division, 821—**The primary objective is to support laboratory programs in the areas of Engineering Metrology, Large-Scale Metrology, Nanometer-Scale Metrology, and Surface Metrology. The contact person for this division is: Dr. Dennis Swyt, and he may be reached at (301) 975-3463; [dennis.swyt@nist.gov](mailto:dennis.swyt@nist.gov).

**II. Manufacturing Metrology Division, 822—**The primary objective is to support laboratory programs in Mechanical Metrology; Advanced Optics Metrology; Predictive Process Engineering; and Smart Machine Tools. The contact person for this division is: Dr. E. Clayton Teague, and he may be reached at (301) 975-6600; [clayton.teague@nist.gov](mailto:clayton.teague@nist.gov).

**III. Intelligent Systems Division, 823—**The primary objective is to support laboratory programs in Intelligent Open Architecture Control of Manufacturing Systems, Intelligent Controls of Mobility Systems, and Intelligent Systems. The contact person for this division is: Mr. Albert Wavering, and he may be reached at (301) 975-3418; [albert.wavering@nist.gov](mailto:albert.wavering@nist.gov).

**IV. Manufacturing Systems Integration Division, 826—**The primary objective is to pursue semantics- and ontology-based systems integration technology and standards through support of laboratory programs in Manufacturing Enterprise Integration; Manufacturing Simulation and Visualization; Integrated Simulations for Homeland Defense and Emergency Response; Product Engineering; Healthcare Informatics; and Meso-Micro-Nano-Manufacturing. The contact person for this division is: Dr. Steven R. Ray, and he may be reached at (301) 975-3508; [steven.ray@nist.gov](mailto:steven.ray@nist.gov).

**Eligibility:** The MEL Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** In fiscal year 2003, the MEL Grants Program anticipates funding of approximately \$750,000, including new awards and continuing projects. Individual awards are expected to range from approximately \$25,000 to \$300,000.

**Proposal Review Process:** Responsive proposals will be reviewed in a two-step process. First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the section above that the proposal addresses will conduct a technical review of proposals,



based on the evaluation criteria described below. Reviews will be conducted no less than once per quarter, and all proposals since the last review session will be ranked based on the reviewers' scores. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but ranks will be determined on an individual basis, not as a consensus. Second, the Division Chief or Laboratory Director will make application selections.

In making application selections, the Division Chief or Laboratory Director will take into consideration the results of the reviewers' evaluations, the compatibility of the applicant's proposal with the program objectives of the particular division that the proposal addresses, the availability of funds, and relevance to the objectives of the MEL Grants Program. These objectives are described above in the Program Objectives. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final.

**Evaluation Criteria:** For the MEL Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. **Rationality.** Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. **Technical Merit of Contribution.** Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of manufacturing engineering and metrology research.

3. **Qualifications of Technical Personnel.** Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

4. **Resources Availability.** Reviewers will consider the extent to which the proposer has access to the necessary NIST or other facilities and overall support to accomplish project objectives.

Each of these factors will be given equal weight in the evaluation process.

**Award Period:** For the MEL Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the MEL program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (i.e., the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

**Matching Requirements:** The MEL Grants Program does not require any matching funds.

**Application Kit:** An application kit, containing all required application forms and certifications is available by electronic mail to: Mrs. Barbara Horner, [barbara.horner@nist.gov](mailto:barbara.horner@nist.gov). Alternatively, Mrs. Horner can be contacted at (301) 975-4345.

#### **Chemical Science and Technology Laboratory Grants Program**

**Dates:** The Chemical Science and Technology Laboratory Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds.

**Addresses:** For the Chemical Science and Technology Laboratory Grant Program applicants are requested to submit one signed original and two copies of the proposal clearly marked to identify the field of research to: Attn: Dr. William F. Koch, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8300, Gaithersburg, MD 20899-8300. Tel (301) 975-8301. E-Mail: [william.koch@nist.gov](mailto:william.koch@nist.gov).

**Authority:** As authorized under 15 U.S.C. 272 (b) and (c), the Chemical Science and Technology Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** All proposals submitted to the Chemical Science and Technology Laboratory Grants Program must be in accordance with the program objectives and programs listed below. Proposals submitted to the CSTL Grants Program must address a specific measurement issue relevant to one of the stated CSTL Programs, and must be directed to a specific Division. The appropriate Division Chief for each field of research may be contacted for clarification of the program objectives. Additional information about the Divisions and CSTL Programs may be obtained at the following Web site: <http://www.cstl.nist.gov/>.

CSTL is the United States' primary reference laboratory for chemical measurements, entrusted with developing, maintaining, advancing, and enabling the Nation's chemical measurement system, thereby enhancing industry's productivity and competitiveness, establishing comparability of measurements to facilitate equity of global trade, and improving public health, safety, and environmental quality. CSTL focuses its activities in measurement science research on reference methods, reference materials and reference data, and directs these efforts in support of the following specific Program areas aligned with industrial segments and National priorities:

1. Automotive and Aerospace;
2. Biomaterials;
3. Pharmaceuticals and Biomanufacturing;
4. Chemical and Allied Products;
5. Energy Systems;
6. Environmental Technologies and Services;
7. Food and Nutritional Products;
8. Forensics and Homeland Security;
9. Health and Medical Products and Services;
10. Industrial and Analytical Instruments and Services;
11. Microelectronics.

These Programs are structured to support CSTL's three objectives:

- Provide the national traceability and international comparability structure for measurements in chemistry, chemical engineering, and biotechnology.
- Assure that U.S. industry has access to accurate and reliable data and predictive models to determine the chemical and physical properties of materials and processes.
- Anticipate and address next-generation measurement needs of the Nation. CSTL conducts its research and is organized along disciplinary lines:

**Biotechnology Division:** DNA chemistry, sequencing; Protein



structure, properties, and modeling; Biomaterials; Biocatalysis and bioprocessing measurements. The contact person for this division is: Dr. Vincent L. Vilker, and he may be reached at (301) 975-2629.

*Process Measurements Division:* Research, calibration services and provision of primary standards for temperature, pressure, vacuum, humidity, fluid flow, air speed, liquid density and volume, and gaseous leak-rate measurements; Sensor research. The contact person for this division is: Dr. James R. Whetstone, and he may be reached at (301) 975-2609.

*Surface and Microanalysis Science Division:* Nanoscale chemical characterization; Particle characterization and standards; Electronic and advanced materials characterization; Surface and interface chemistry; Advanced isotope metrology. The contact person for this division is: Dr. Richard R. Cavanagh, and he may be reached at (301) 975-2368.

*Physical and Chemical Properties Division:* Basic reference data; Data for process and product design; Properties of energy-related fluids; Fundamental studies of fluids; Cryogenic technologies; Computational chemistry. The contact person for this division is: Dr. Mickey Haynes, and he may be reached at (303) 497-3247.

*Analytical Chemistry Division:* Chemical measurements research and services in: Analytical sensing technologies; Classical analytical methods; Gas metrology; Laboratory automation technology; Nuclear analytical methods; Organic analytical methods; and Spectrochemical measurement methods. The contact person for this division is: Dr. Willie E. May, and he may be reached at (301) 975-3108.

*Eligibility:* The Chemical Science and Technology Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

*Funding Availability:* In fiscal year 2003, the Chemical Science and Technology Laboratory anticipates funding of approximately \$1,000,000. Individual awards are expected to range from approximately \$5,000 to \$100,000.

No funds have been set aside specifically for support of the CSTL Grants Program. The availability of funds depends upon actual authorization of funds and other costs expected to be incurred by individual

divisions within the laboratory. Where funds are identified as available for grants, those funds will be awarded to highly ranked proposals as determined by the process described in this notice.

*Proposal Review Process:* For the Chemical Science and Technology Laboratory Grants Program, proposals will be reviewed in a three-step process. First, the Deputy Director of CSTL, or appropriate CSTL Division Chief, will determine the compatibility of the applicant's proposal with CSTL Program Areas, the alignment of the measurement issue that the proposal addresses with division activities, and the relevance to the objectives of the Chemical Science and Technology Laboratory Grants Program. These objectives are described in the "Program Objectives" section. If it is determined that the proposal is incomplete or non-responsive to the scope of the stated objectives, the proposal will not be reviewed for technical merit. If it is determined that all funds available for the CSTL Grants Program for the given year have been exhausted, the proposal will not be reviewed for technical merit. If a proposal is determined to be incomplete or non-responsive, or if it is determined that all available funds have been exhausted, the CSTL Grants Program will retain one copy of the proposal for three years for record keeping purposes. The remaining copies will be destroyed.

Second, at least three independent, objective individuals knowledgeable about the particular measurement science area described in the section above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. Reviews will be conducted on a quarterly basis, and all responsive, complete proposals received and reviewed since the last quarter will be ranked based on the reviewers' scores. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but ranks will be determined on an individual basis, not as a consensus.

Third, the Division Chief will make application selections, taking into consideration the results of the reviewers' evaluations, the availability of funds, and the relevance of the proposal to the programmatic priorities of the Division described in the Program Description and Objectives section above.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance

with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decisions of the Grants Officer are final.

*Evaluation Criteria:* For the Chemical Science and Technology Laboratory Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. *Rationality.* Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. *Qualifications of Technical Personnel.* Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. *Resources Availability.* Reviewers will consider the extent to which the proposer has access to the necessary facilities and overall support to accomplish project objectives.

4. *Technical Merit of Contribution.* Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of measurement science, especially as it pertains to reference methods, reference materials and reference data in Chemical Science and Technology.

Each of these factors will be given equal weight in the evaluation process.

*Award Period:* For the Chemical Science and Technology Laboratory Grant Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Chemical Science and Technology Laboratory program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (i.e. the scopes of work for each funding period must produce identifiable and

meaningful results in and of themselves).

**Matching Requirements:** The Chemical Science and Technology Laboratory Grants Program does not require any matching funds.

**Contact:** For information on the Chemical Science and Technology Laboratory Grants Program, please contact Dr. William Koch, (301) 975-8301.

**Application Kit:** For the CSTL Grants Program, an application kit, containing all required application forms and certifications is available by contacting Mr. Neil Alderoty, (301) 975-8303.

### Physics Laboratory Grants Program

**Dates:** The Physics Laboratory Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds.

**Addresses:** For the Physics Laboratory Grant Program applicants are requested to submit one signed original and two copies of the proposal clearly marked to identify the field of research to: Attn. Ms. Anita Sweigert, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8400, Gaithersburg, MD 20899-8400. Tel (301) 975-4200. E-Mail: [anita.sweigert@nist.gov](mailto:anita.sweigert@nist.gov).

**Authority:** As authorized under 15 U.S.C. 272 (b) and (c), the Physics Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** All proposals submitted to the Physics Laboratory Grants Program must be in accordance with the program objectives listed below. The appropriate Program Manager for each field of research may be contacted for clarification of the program objectives.

**I. Electron and Optical Physics Division, 841—**The objective is to supplement division activities in characterization of nanometer-scale electronic and magnetic structures, characterization of EUV optical components to support semiconductor lithography and ultraviolet radiometric metrology, and to support ongoing activities in Bose-Einstein condensation and quantum information. The contact person for this division is: Dr. Charles W. Clark and he may be reached at (301) 975-3709.

**II. Atomic Physics Division, 842—**The primary objective is to support division programs aimed at determining basic atomic properties and developing new metrology techniques in atomic

spectroscopy, quantum processes, plasma radiation, laser cooling and trapping, and quantum metrology. The contact person for this division is: Dr. Wolfgang L. Wiese and he may be reached at (301) 975-3200.

**III. Optical Technology Division, 844—**The primary objective is to develop, improve and maintain national standards for radiation thermometry, spectroradiometry, photometry, and spectrophotometry as well as conduct basic theoretical and experimental research on the photophysical and photochemical properties of materials, in radiometric and spectroscopic techniques and instrumentation, and in the application of optical technologies. The contact person for this division is: Dr. Albert C. Parr and he may be reached at (301) 975-2316.

**IV. Ionizing Radiation Division, 846—**The primary objective is to provide primary standards, measurement methods, and technology to support the Division's work in meeting national needs in radiation interactions and dosimetry, neutron interactions and dosimetry, and radioactivity including both theoretical/experimental and applied research programs in Homeland Security and Health Care. The contact person for this division is: Dr. Bert M. Coursey and he may be reached at (301) 975-5584.

**V. Time and Frequency Division, 847—**The primary objective is to supplement division basic and applied research programs in the areas of phase noise measurements, network synchronization, ion storage, atomic standards and optical frequency measurements in support of future standards, dissemination services, and measurement methods. The contact person for this division is: Dr. Donald B. Sullivan and he may be reached at (303) 497-3772.

**Eligibility:** The Physics Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** In fiscal year 2003, the Physics Laboratory anticipates funding of approximately \$2,000,000, including new awards and continuing projects. Funding availability will be apportioned by quarter. Individual awards are expected to range from approximately \$5,000 to \$300,000.

**Proposal Review Process:** For the Physics Laboratory Grants Program, responsive proposals will be considered as follows: first, at least three

independent, objective individuals knowledgeable about the particular scientific area described in the section above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. Reviews will be conducted on a monthly basis, and all proposals received during the month will be ranked based on the reviewers' scores. If non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus.

Next, the Division Chief will make final application selections, taking into consideration the results of the reviewers' evaluations, including rank; the compilation of a slate that, when taken as a whole, is likely to best further the program goals described above; and the availability of funds.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible.

Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award.

The decisions of the Grants Officer are final.

**Evaluation Criteria:** For the Physics Laboratory Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. **Rationality.** Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. **Qualifications of Technical Personnel.** Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. **Resources Availability.** Reviewers will consider the extent to which the proposer has access to the necessary NIST or other facilities and overall support to accomplish project objectives.

4. **Technical Merit of Contribution.** Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of physics.

Each of these factors will be given equal weight in the evaluation process.

**Award Period:** For the Physics Laboratory Grant Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year project is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Physics Laboratory program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, *i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

**Matching Requirements:** The Physics Laboratory Grants Program does not require any matching funds.

**Application Kit:** For the Physics Laboratory Grants Program, an application kit, containing all required application forms and certifications is available by contacting Ms. Anita Sweigert, (301) 975-4201.

### MSEL Grants Program

**Dates:** The MSEL Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds. Each applicant must submit one signed original and two copies of each proposal along with a Grant Application, (Standard Form 424 REV. 7/97 and other required forms).

**Addresses:** For the MSEL Grants Program, submit one signed original and two copies of the proposal, clearly marked to identify the field of research, to: Materials Science and Engineering Laboratory, Attn.: Ms. Marlene Taylor, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8501, Building 223, Room A305, Gaithersburg, Maryland 20899-8501. Tel: (301) 975-5653. E-mail: [marlene.taylor@nist.gov](mailto:marlene.taylor@nist.gov).

**Authority:** The authority for the MSEL Grants Program is as follows: as authorized under 15 U.S.C. 272 (b) and (c), the MSEL

conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** All proposals submitted to the MSEL Grants Program must be in accordance with the program objectives listed below. The appropriate Program Manager for each field of research may be contacted for clarification of the program objectives.

**I. Laboratory Office, 850—**The primary objective is to supplement Materials Science and Engineering Laboratory activities of importance to materials science generally, including portions of Federal research and development programs performed in concert with other Federal agencies; and theoretical and computational materials science. The contact person for the Laboratory Office is: Dr. Stephen W. Freiman and he may be reached at (301) 975-5658 or by e-mail at [stephen.freiman@nist.gov](mailto:stephen.freiman@nist.gov).

**II. Ceramics Division, 852—**The primary objective is to supplement division activities in the area of combinatorial tools, nanotribology, nano- and micro-electronic materials, dielectric ceramics, interfacial chemistry, and microstructural analysis. The contact person for this division is: Dr. Ronald Munro and he may be reached at (301) 975-6127 or by e-mail at [ronald.munro@nist.gov](mailto:ronald.munro@nist.gov).

**III. Materials Reliability Division, 853—**The primary objective is to supplement division activities in the area of micro- and nano-scale property measurement. The contact person for this division is: Dr. Thomas Siewert and he may be reached at (303) 497-3523 or by e-mail at [siewert@boulder.nist.gov](mailto:siewert@boulder.nist.gov).

**IV. Polymers Division, 854—**The primary objective is to support division programs in electronics materials, biomaterials, combinatorial methods, nano-structured materials and processing characterization through participation in research on metrology, synthesis, processing and characterization of structure, mechanical, thermal and electrical properties. The contact person for this division is: Dr. Bruno Fanconi and he may be reached at (301) 975-6769 or by e-mail at [bruno.fanconi@nist.gov](mailto:bruno.fanconi@nist.gov).

**V. Metallurgy Division, 855—**The primary objective is to develop techniques to predict, measure and control transformations, phases, microstructure and kinetic processes as well as mechanical, physical and chemical properties in metals and their alloys. The contact person for this division is: Dr. Frank W. Gayle and he may be reached at (301) 975-6161 or by e-mail at [frank.gayle@nist.gov](mailto:frank.gayle@nist.gov).

**VI. NIST Center for Neutron Research, 856—**The primary objective is to develop high resolution cold and thermal neutron scattering research approaches and related physics, chemistry, macromolecular and materials applications. Awards to universities for participation by university students in the NIST/NSF Center for High Resolution Scattering are also funded under this program. The contact person for this division is: Dr. John J. Rush and he may be reached at (301) 975-6231 or by e-mail at [john.rush@nist.gov](mailto:john.rush@nist.gov).

**Eligibility:** The MSEL Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** In fiscal year 2003, the MSEL Grants Program anticipates funding of approximately \$6,000,000, including new awards and continuing projects. Most grants and cooperative agreements are expected to be in the \$25,000 to \$100,000 per year range.

**Proposal Review Process:** For the MSEL Grants Program proposals will be reviewed in a two-step process. First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the section above that the proposal addresses will conduct a technical review of proposals, as they are received on a rolling basis, based on the evaluation criteria. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but ranks will be determined on an individual basis, not as a consensus. Second, the Division Chief or Center Director will make application selections. In making application selections, the Division Chief or Center Director will take into consideration the results of the reviewers' evaluations, the compatibility of the applicant's proposal with the program objectives of the particular division or center that the proposal addresses, the availability of funds, and relevance to the objectives of the MSEL Grants Program. These objectives are described above in the "Program Objectives" section. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that

best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final.

**Evaluation Criteria:** For the MSEL Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. **Rationality.** Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. **Qualifications of Technical Personnel.** Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. **Resources Availability.** Reviewers will consider the extent to which the proposer has access to the necessary NIST or other facilities and overall support to accomplish project objectives.

4. **Technical Merit of Contribution.** Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of materials science and engineering and neutron research.

Each of these factors will be given equal weight in the evaluation process.

**Award Period:** For the MSEL Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the MSEL program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (i.e., the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

**Matching Requirements:** The MSEL Grants Program does not require any matching funds.

**Application Kit:** For the MSEL Grants Program, an application kit, containing all required application forms and certifications is available by contacting Ms. Marlene Taylor, (301) 975-5653.

#### **Building Research Grants and Cooperative Agreements Program**

**Dates:** The Building Research Grants and Cooperative Agreements Program proposals must be received no later than the close of business September 30, 2003. Proposals received after June 30, 2003 will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds.

**Addresses:** For the Building Research Grants and Cooperative Agreements Program, submit one signed original and two copies of the proposal package to: Building and Fire Research Laboratory, Attn.: Karen Perry, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8602, Gaithersburg, MD 20899-8602. Tel.: (301) 975-5910. Fax: (301) 975-4032.

**Authority:** As authorized by 15 U.S.C. 272(b) and (c), the NIST Building and Fire Research Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

**Program Description and Objectives:** The Building Research Grants and Cooperative Agreements Program supports the formal mission of the Building and Fire Research Laboratory, which is to meet the measurement and standards needs of the Building and Fire communities. All proposals submitted must be in accordance with the program objectives listed below. The appropriate Program Manager for each field of research may be contacted for clarification of the program objectives.

1. **Materials and Construction Research Division, 861**—The primary objective is to support laboratory programs in the areas of Structures, Construction Metrology and Automation, Inorganic Materials, and Polymeric Materials (including safety, security, and sustainability of building and physical infrastructure, service-life performance of building materials, and construction cycle time). The contact person for this division is: Dr. Shyam Sunder, and he may be reached at (301) 975-6713.

2. **Building Environment Division, 863**—The primary objective is to support laboratory programs in the areas of Thermal Machinery, Mechanical Systems and Controls, Heat Transfer and Alternative Energy Systems, Computer Integrated Construction and Indoor Air Quality and Ventilation (including cybersecurity, critical

infrastructure protection of building management and control systems, and life-cycle information management in buildings). The contact person for this division is: Dr. George E. Kelly, and he may be reached at (301) 975-5850.

For details on these various activities, please see the Building and Fire Research Laboratory website at <http://www.bfsl.nist.gov>. Note that documents describing the current programs for the two technical divisions are available through the homepage.

**Eligibility:** The Building Research Grants and Cooperative Agreements Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** Over the past three years, the building divisions of the Building and Fire Research Laboratory funded a total of approximately \$1,000,000 in grants and cooperative agreements. The amount available each year fluctuates considerably based on programmatic needs. Individual awards are expected to range between \$5,000 and \$150,000.

**Proposal Review Process:** All applications received in response to this announcement will be reviewed to determine whether or not they are complete and responsive. Incomplete or non-responsive applications will not be reviewed for technical merit. The Program will retain one copy of each non-responsive application for three years for recordkeeping purposes. The remaining copies will be destroyed.

Responsive proposals will be forwarded to the appropriate Division Chief, who will assign them to appropriate reviewers. At least three independent, objective individuals knowledgeable about the particular scientific area described above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. When non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. Reviews will be conducted no less than once per quarter, and all proposals since the last review session will be ranked based on the reviewers' scores.

Next, the Division Chief or Laboratory Director will make application selections. In making application selections, the Division Chief or Laboratory Director will take into consideration the results of the

evaluations, the scores of the reviewers, the availability of funds, and relevance to the objectives of the Building Systems Research Grants and Cooperative Agreements Program, as described in the Program Description and Objectives section for this program.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The award decision of the Grants Officer is final. Applicants should allow up to 90 days processing time. The Program will retain one copy of each application that is not funded for three years for recordkeeping purposes. The remaining copies will be destroyed.

**Evaluation Criteria:** The Divisions will score proposals based on the following criteria and weights:

1. *Technical quality of the research.* Reviewers will assess the rationality, innovation and imagination of the proposal and the fit to NIST's in-house building research programs. (0–35 points)

2. *Potential impact of the results.* Reviewers will assess the potential impact and the technical application of the results to our in-house programs and the building industry. (0–25 points)

3. *Staff and institution capability to do the work.* Reviewers will evaluate the quality of the facilities and experience of the staff to assess the likelihood of achieving the objective of the proposal. (0–20 points)

4. *Match of budget to proposed work.* Reviewers will assess the budget against the proposed work to ascertain the reasonableness of the request. (0–20 points)

**Award Period:** For the Building Research Grants and Cooperative Agreements Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of

NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Building Research Grants and Cooperative Agreements Program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

**Matching Requirements:** The Building Research Grants and Cooperative Agreements Program does not require any matching funds.

**Application Kit:** An application kit, containing all required application forms and certifications is available by contacting: Karen Perry, (301) 975–5910.

#### Fire Research Grants Program

**Dates:** The Fire Research Grants Program proposals must be received no later than the close of business September 30, 2003. Proposals received after April 30, 2003, will continue to be processed and considered for funding but may be funded in the next fiscal year, subject to the availability of funds.

**Addresses:** For the Fire Research Grants Program submit one signed original and two copies of the proposal to: Building and Fire Research Laboratory (BFRL), Attn.: Ms. Wanda Duffin, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8660, Gaithersburg, Maryland 20899–8660. Tel: (301) 975–6863. E-mail: [wanda.duffin@nist.gov](mailto:wanda.duffin@nist.gov). Web site: <http://www.bfrl.nist.gov>.

**Authority:** As authorized by 15 U.S.C. 278f, the NIST Building and Fire Research Laboratory conducts directly and through grants and cooperative agreements, a basic and applied fire research program.

**Program Description and Objectives:** The program description and objectives for the Fire Research Grants Program are as follows:

A. *Analysis and Prediction:* The objectives are to develop understanding and predictive methods for dynamic fire phenomena to advance fire science and engineering practice and to perform research to understand the heat and mass transfer processes occurring in fires in order to improve predictions of the growth, spread, suppression, and emissions transport from fires of all scales. Experiments and metrology are developed and used to develop, support, and verify advanced computer

simulations of fire phenomena, fire hazards, fire protection, and fire fighting. The contact person for this group is: Dr. Anthony Hamins, and he may be reached at (301) 975–6598.

B. *Fire Metrology:* The objective is to apply measurement science in the development and quantification of new and existing measurement methods for studying fire growth, fire-induced flows, flame radiation, smoke formation and dynamics, species production, heat transfer, fire suppression, and fire detection. The contact person for this group is: Dr. George Mulholland, and he may be reached at (301) 975–6695.

C. *Fire Fighting Technology:* The objectives are to conduct research that enables advances in fire fighter safety, fire ground operations, and effectiveness of the fire service; develop and apply measurements, modeling, and technology, and improve the understanding of the behavior, prevention and control of fires to enhance: fire fighting operations and equipment, fire suppression, fire investigations, and disaster response; and provide input, including experimental data, fire modeling and test protocols, to advance the effectiveness of fire safety standards and codes. The contact person for this group is Mr. Nelson Bryner, and he may be reached at (301) 975–6868.

D. *Integrated Performance Assessment:* The objective is to produce tools utilizing enhanced data and prediction methods to quantify fire events for fire hazard and risk assessment; for fire fighting operations and training; for fire investigations; and for performance evaluations of fire protection systems in buildings, transportation systems, and vehicles in response to fire. Stakeholders include architects and design engineers; manufacturers of building materials, products, and furnishings; code developers, enforcers, and regulatory authorities; and those exposed to direct risk such as building owners, occupants, the fire service, and the general public. The contact person for this group is: Dr. Kathy Notarianni, and she can be reached at (301) 975–6883.

E. *Materials and Products:* The objective is to perform research enabling the confident development by industry of new, less-flammable materials and products. This capability is based on understanding fundamentally the mechanisms that control the ignition, flame spread and burning rate of materials, as well as and the chemical and physical characteristics that affect these aspects of flammability. This includes: Developing methods of measuring the response of a material to

fire conditions that enable assured prediction of the full-scale performance of the final product; developing computational molecular dynamics and other mechanistic approaches to understand flame retardant mechanisms and the effects of polymer chemical structure on flammability; characterizing the burning rates of charring and non-charring polymers and composites; and delineating and modeling the enthalpy and mass transfer mechanisms of materials combustion. The contact person for this group is Dr. Jeffrey Gilman, and he can be reached at (301) 975-6573.

**Eligibility:** The Fire Research Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; State, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

**Funding Availability:** For the Fire Research Grants Program, the annual budget is approximately \$1.3 million. Because of commitments for the support of multi-year projects and because proposals may have been deferred from the previous year's competition, only a portion of the budget is available to fund applications received in response to this notice. Most grants and cooperative agreements are in the \$10,000 to \$100,000 per year range, with a maximum requested duration of three years.

**Proposal Review Process:** Prospective proposers are encouraged to contact the above researchers to determine the extent of interest prior to preparation of a detailed proposal. Responsive proposals will be assigned, as received on a rolling basis, to the appropriate group leader of the five programs listed above in the program description and objectives. Proposals are evaluated for technical merit based on the evaluation criteria described below by at least three reviewers chosen from NIST professionals, technical experts from other interested government agencies, and experts from the fire research community at large. When non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. Group leaders will make funding recommendations to the Division Chief based on the technical evaluation score and the relationship of the work proposed to the objectives of the program.

In making application selections, the Division Chief will take into consideration the results of the

evaluations, the scores of the reviewers, the group leader's recommendation, the availability of funds, and relevance to the objectives of the Fire Research Grants Program, as described in the Program Description and Objectives section for this program. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The award decision of the Grants Officer is final. Applicants should allow up to 90 days processing time.

**Evaluation Criteria:** For the Fire Research Grants Program, the technical evaluation criteria are as follows:

- a. *Technical quality of the research.* Reviewers will assess the rationality, innovation and imagination of the proposal and the fit to NIST's in-house fire research program. (0-35 points).
- b. *Potential impact of the results.* Reviewers will assess the potential impact and the technical application of the results to our in-house programs and the fire safety community. (0-25 points)
- c. *Staff and institution capability to do the work.* Reviewers will evaluate the quality of the facilities and experience of the staff to assess the likelihood of achieving the objective of the proposal. (0-20 points)
- d. *Match of budget to proposed work.* Reviewers will assess the budget against the proposed work to ascertain the reasonableness of the request. (0-20 points)

**Award Period:** For the Fire Research Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year project is approved, funding will initially be provided for only the first year of the program. If an application is selected for funding, DoC has no obligation to provide any additional future funding in connection with that award. Funding for each subsequent year of a multi-year proposal will be contingent on satisfactory progress, continuing relevance to the mission of the NIST Fire Research Program, and the availability of funds.

**Matching Requirements:** The Fire Research Grants Program does not require any matching funds.

**Application Kit:** For the Fire Research Grants Program, an application kit, containing all required application forms and certifications is available by contacting Ms. Wanda Duffin, (301) 975-6863, Web site: <http://www.bfrl.nist.gov>.

**Additional Information:** The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of October 1, 2001 (66 FR 49917), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109), are applicable to this solicitation. In addition, the following information is applicable to all programs described above.

**Collaborations with NIST Employees:** All applications should include a description of any work proposed to be performed by an entity other than the applicant, and the cost of such work should ordinarily be included in the budget.

If an applicant proposes collaboration with NIST, the statement of work should include a statement of this intention, a description of the collaboration, and prominently identify the NIST employee(s) involved, if known. Any collaboration by a NIST employee must be approved by appropriate NIST management and is at the sole discretion of NIST. Prior to beginning the merit review process, NIST will verify the approval of the proposed collaboration. Any unapproved collaboration will be stricken from the proposal prior to the merit review.

**Use of NIST Intellectual Property:** If the applicant anticipates using any NIST-owned intellectual property, to carry out the work proposed, the applicant should identify such intellectual property. This information will be used to ensure that no NIST employee involved in the development of the intellectual property will participate in the review process for that competition. In addition, if the applicant intends to use NIST-owned intellectual property, the applicant must comply with all statutes and regulations governing the licensing of Federal government patents and inventions, described at 35 U.S.C. sec. 200-212, 37 CFR part 401, 15 CFR 14.36, and in section 20 of the Department of Commerce Pre-Award Notification Requirements, 66 FR 49917 (2001), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109). Questions about these requirements may be directed to the Counsel for NIST, 301-975-2803.

Any use of NIST-owned intellectual property by a proposer is at the sole discretion of NIST and will be negotiated on a case-by-case basis if a project is deemed meritorious. The applicant should indicate within the statement of work whether it already has a license to use such intellectual property or whether it intends to seek one.

If any inventions made in whole or in part by a NIST employee arise in the course of an award made pursuant to this notice, the United States government may retain its ownership rights in any such invention. Licensing or other disposition of NIST's rights in such inventions will be determined solely by NIST, and include the possibility of NIST putting the intellectual property into the public domain.

**Funding Availability:** For all Financial Assistance programs listed above, awards are contingent on the availability of funds.

**Catalog of Federal Domestic Assistance Name and Number:** Measurement and Engineering Research and Standards—11.609.

**For Further Information Contact:** All grants related administration questions concerning these programs should be directed to the NIST Grants and Agreements Management Division at (301) 975-6328.

Where websites are referenced within this notice, those without internet access may contact the appropriate Program official to obtain information.

**Initial Screening of all Applications:** All applications received in response to this announcement will be reviewed to determine whether or not they are complete and responsive to the scope of the stated objectives for each program. Incomplete or non-responsive applications will not be reviewed for technical merit. The Program will retain one copy of each non-responsive application for three years for record keeping purposes. The remaining copies will be destroyed.

**Fees and/or Profit:** It is not the intent of NIST to pay fee or profit for any of the financial assistance awards that may be issued pursuant to this announcement.

**Automated Standardized Application for Payment System (ASAP):** During FY 2002 and becoming mandatory in FY 2003, the Department of Commerce will begin using the Department of Treasury's ASAP. NIST began using the ASAP system in July 2001 and continues to establish new accounts in ASAP. Awards made pursuant to this announcement may contain the ASAP payment clause. In order to receive

payments for services under these awards, recipients will be required to register with the Department of Treasury and indicate whether or not they will use the on-line or voice response method of withdrawing funds from their ASAP established accounts. More information regarding ASAP can be found on-line at <http://www.fms.treas.gov/asap/index.html>.

**Paperwork Reduction Act:** The standard forms in the application kit involve a collection of information subject to the Paperwork Reduction Act. The use of Standard Forms 424, 424A, 424B, SF-LLL, and CD-346 have been approved by OMB under the respective Control Numbers 0348-0043, 0348-0044, 0348-0040, 0348-0046, and 0605-0001.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

**Research Projects Involving Human Subjects, Human Tissue, Data or Recordings Involving Human Subjects:** Any proposal that includes research involving human subjects, human tissue, data or recordings involving human subjects must meet the requirements of the Common Rule for the Protection of Human Subjects, codified for the Department of Commerce at 15 CFR part 27. In addition, any proposal that includes research on these topics must be in compliance with any statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other federal agencies regarding these topics, all regulatory policies and guidance adopted by DHHS, FDA, and other Federal agencies on these topics, and all Presidential statements of policy on these topics.

On December 3, 2000, the U.S. Department of Health and Human Services (DHHS) introduced a new Federalwide Assurance of Protection of Human Subjects (FWA). The FWA covers all of an institution's Federally-supported human subjects research, and eliminates the need for other types of Assurance documents. The Office for Human Research Protections (OHRP) has suspended processing of multiple project assurance (MPA) renewals. All existing MPAs will remain in force until further notice. For information about FWAs, please see the OHRP Web site at <http://ohrp.osophs.dhhs.gov/irbasur.htm>.

In accordance with the DHHS change, NIST will continue to accept the submission of human subjects protocols that have been approved by Institutional Review Boards (IRBs) possessing a current, valid MPA from DHHS. NIST also will accept the submission of human subjects protocols that have been approved by IRBs possessing a current, valid FWA from DHHS. NIST will not issue a single project assurance (SPA) for any IRB reviewing any human subjects protocol proposed to NIST.

On August 9, 2001, the President announced his decision to allow Federal funds to be used for research on existing human embryonic stem cell lines as long as prior to his announcement (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being. NIST will follow guidance issued by the National Institutes of Health at <http://escr.nih.gov/> for funding such research.

**Research Projects Involving Vertebrate Animals:** Any proposal that includes research involving vertebrate animals must be in compliance with the National Research Council's "Guide for the Care and Use of Laboratory Animals" which can be obtained from National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20055. In addition, such proposals must meet the requirements of the Animal Welfare Act (7 U.S.C. 2131 *et seq.*), 9 CFR parts 1, 2, and 3, and if appropriate, 21 CFR part 58. These regulations do not apply to proposed research using pre-existing images of animals or to research plans that do not include live animals that are being cared for, euthanased, or used by the project participants to accomplish research goals, teaching, or testing. These regulations also do not apply to obtaining animal materials from commercial processors of animal products or to animal cell lines or tissues from tissue banks.

**Matching Funds:** Although many of the programs described in this notice do not require cost share, if it is determined that your proposal falls within the authority of 19 U.S.C. 2543-45 cost share will be required as follows:

Pursuant to 19 U.S.C. 2543-45, financial assistance shall not exceed 75 percent of such program or activity, when the primary purpose of such program or activity is—

(1) To increase the awareness of proposed and adopted standards-related activities;



(2) To facilitate international trade through the appropriate international and domestic standards-related activities;

(3) To provide adequate United States representation in international standards-related activities; and

(4) To encourage United States exports through increased awareness of foreign standards-related activities that may affect United States exports.

**Type of Funding Instrument:** The funding instrument will be a grant or cooperative agreement, depending on the nature of the proposed work. A grant will be used unless NIST is "substantially involved" in the project, in which case a cooperative agreement will be used. A common example of substantial involvement is collaboration between NIST scientists and recipient scientists or technicians. Please see the DoC Grants and Cooperative Agreements Interim Manual which may be found on the Internet at [http://www.osc.doc.gov/oebam/GCA\\_manual.htm](http://www.osc.doc.gov/oebam/GCA_manual.htm). NIST will make decisions regarding the use of a cooperative agreement on a case-by-case basis. Funding for contractual arrangements for services and products for delivery to NIST is not available under this announcement.

If a proposal submitted under this Notice is not properly funded by a grant or cooperative agreement, NIST will consider whether the proposal may be appropriately funded through procurement, interagency agreement, or another mechanism that does not involve a grant or cooperative agreement. NIST's review and consideration of that proposal will be consistent with the requirements applicable to that funding mechanism.

**Indirect Costs:** For the EEEL, MEL, CSTL, Physics, MSEL, BFRL, and ITL SURF Programs, no Federal funds will be authorized for Indirect Costs (IDC) nor fringe benefits; however, an applicant may provide for IDC and/or fringe benefits under his/her portion of Cost Sharing.

**Classification:** This funding notice was determined to be "not significant" for purposes of Executive Order 12866.

It has been determined that this notice does not contain policies with federalism implications as that term is defined in Executive Order 13132.

Applications under these programs are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Because notice and comment are not required under 5 U.S.C. 553, or any other law, for notices relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)), a Regulatory

Flexibility Analysis is not required and has not been prepared for this notice, 5 U.S.C. 601 *et seq.*

Dated: February 13, 2003.

**Karen H. Brown,**

*Deputy Director, NIST.*

[FR Doc. 03-4129 Filed 2-19-03; 8:45 am]

**BILLING CODE 3510-13-U**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Proposed Collection; Comment Request

**AGENCY:** Office of the Director, Administration and Management.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Director, Administration and Management announces the proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by April 21, 2003.

**ADDRESSES:** Written comments and recommendations on the proposed information collection should be sent to The Office of the Director, Administration and Management/Quality Management Office, ATTN: Ms. Joyce Mussey, 1777 N. Kent St., Suite 14038, Arlington, VA 22209.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Office of the Director, Administration and Management/Quality Management Office (703) 588-8142/8150.

**Title and OMB Number:** Interactive Customer Evaluation System; OMB Number 0704-420.

**Needs and Uses:** The Interactive Customer Evaluation System automates

and minimizes the use of the current manual paper comment cards and other customer satisfaction collection medium, which exist at various customer service locations throughout the Department of Defense.

**Affected Public:** Individuals or Households; Business or Other For-Profit.

**Annual Burden Hours:** 165.

**Number of Respondents:** 3300.

**Responses per Respondent:** 1.

**Average Burden per Response:** 3 minutes.

**Frequency:** On occasion.

#### SUPPLEMENTARY INFORMATION:

#### Summary of Information Collection

Members of the public who respond on the Interactive Customer Evaluation system are authorized customers and have been provided a service through DoD customer service organizations. They have the opportunity to give automated feedback to the service provider on the quality of their experience and their satisfaction level. They also have the opportunity to provide any comments that might be beneficial in improving the process and in turn the service to the customer. This is a management tool for improving customer services.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4069 Filed 2-19-03; 8:45 am]

**BILLING CODE 5001-08-M**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Submission for OMB Review; Comment Request

**ACTION:** Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

**DATES:** Consideration will be given to all comments received by March 24, 2003.

**Title and OMB Number:** Evaluation of Reasons for Non-Acceptance of Department of Army Civilian Jobs Offers; OMB Number 0702-[To Be Determined].

**Type of Request:** New Collection.

**Number of Respondents:** 2,500.

**Responses per Respondent:** 1.

**Annual Responses:** 2,500.

**Average Burden per Response:** 7 minutes.



*Annual Burden Hours:* 292.

*Needs and Uses:* Applicants for Department of Army civilian jobs will be surveyed to assess reasons why they declined Army job offers. The purpose of the survey is to determine which factors contributed to the job candidate's non-acceptance and to make recommendations for improvements.

*Affected Public:* Individuals or Households.

*Frequency:* Semi-Annually.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* Ms. Jacqueline Zeiher.

Written comments and recommendations on the proposed information collection should be sent to Ms. Zeiher at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

*DOD Clearance Officer:* Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4070 Filed 2-19-03; 8:45 am]

BILLING CODE 5001-08-M

## DEPARTMENT OF DEFENSE

### GENERAL SERVICES ADMINISTRATION

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0145]

#### **Federal Acquisition Regulation; Submission for OMB Review; Use of Data Universal Numbering System (DUNS) as Primary Contractor Identification**

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance (9000-0145).

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement

concerning use of data universal numbering system (DUNS) as primary contractor identification. A request for public comments was published in the **Federal Register** at 67 FR 77479 on December 18, 2002. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

**DATES:** Submit comments on or before March 24, 2003.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Laura Smith, Acquisition Policy Division, GSA, (202) 208-7279.

#### **SUPPLEMENTARY INFORMATION:**

##### **A. Purpose**

The Data Universal Numbering System (DUNS) number is the nine-digit identification number assigned by Dun and Bradstreet Information Services to an establishment. The Government uses the DUNS number to identify contractors in reporting to the Federal Procurement Data System (FPDS). The FPDS provides a comprehensive mechanism for assembling, organizing, and presenting contract placement data for the Federal Government. Federal agencies report data on all contracts in excess of \$25,000.00 to the Federal Procurement Data Center which collects, processes, and disseminates official statistical data on Federal contracting. Contracting officers insert the Federal Acquisition Regulation (FAR) provision 52.204-6, Data Universal Numbering System (DUNS) Number in solicitations they expect will result in contracts in excess of \$25,000.00. This provision requires offerors to submit their DUNS number with their offer. If the offeror does not have a DUNS number, the provision provides instructions on obtaining one.

## **B. Annual Reporting Burden**

*Respondents:* 35,694.

*Responses Per Respondent:* 4.00.

*Annual Responses:* 142,776.

*Hours Per Response:* .0200.

(Averaged).

*Total Burden Hours:* 2,852.

*Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (MVA), Room 4035, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0145, Use of Data Universal Numbering System (DUNS) as Primary Contractor Identification, in all correspondence.

Dated: February 13, 2003.

**Laura G. Smith,**

*Director, Acquisition Policy Division.*

[FR Doc. 03-4021 Filed 2-19-03; 8:45 am]

BILLING CODE 6820-EP-P

## DEPARTMENT OF DEFENSE

### GENERAL SERVICES ADMINISTRATION

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0026]

#### **Federal Acquisition Regulation; Submission for OMB Review; Change Order Accounting**

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance (9000-0026).

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning change order accounting. A request for public comments was published in the **Federal Register** at 67 FR 71941 on December 3, 2002. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on

valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

**DATES:** Submit comments on or before March 24, 2003.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:**

Linda Klein, Acquisition Policy Division, GSA (202) 501-3775.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

FAR clause 52.243-6, Change Order Accounting, requires that, whenever the estimated cost of a change or series of related changes exceed \$100,000, the contracting officer may require the contractor to maintain separate accounts for each change or series of related changes. The account shall record all incurred segregable, direct costs (less allocable credits) of work, both changed and unchanged, allocable to the change. These accounts are to be maintained until the parties agree to an equitable adjustment for the changes or until the matter is conclusively disposed of under the Disputes clause. This requirement is necessary in order to be able to account properly for costs associated with changes in supply and research and development contracts that are technically complex and incur numerous changes.

**B. Annual Reporting Burden**

*Respondents:* 8,750.

*Responses Per Respondent:* 18.

*Annual Responses:* 157,500.

*Hours Per Response:* .084.

*Total Burden Hours:* 13,230.

**C. Annual Recordkeeping Burden**

*Recordkeepers:* 8,750.

*Hours Per Recordkeeper:* 1.5.

*Total Recordkeeping Burden Hours:* 13,125.

*Total Burden Hours:* 26,355.

*Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from

the General Services Administration, FAR Secretariat (MVA), Room 4035, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0026, Change Order Accounting, in all correspondence.

Dated: February 11, 2003.

**Ralph J. Destefano,**

*Acting Director, Acquisition Policy Division.*

[FR Doc. 03-4101 Filed 2-19-03; 8:45 am]

**BILLING CODE 6820-EP-P**

**DEPARTMENT OF DEFENSE**

**GENERAL SERVICES  
ADMINISTRATION**

**NATIONAL AERONAUTICS AND  
SPACE ADMINISTRATION**

[OMB Control No. 9000-0130]

**Federal Acquisition Regulation;  
Submission for OMB Review; Buy  
American Act—North American Free  
Trade Agreement—Israeli Trade Act  
Certificate**

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for an extension to an existing OMB clearance (9000-0130).

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Buy American Act—North American Free Trade Agreement—Israeli Trade Act Certificate. A request for public comments was published at 67 FR 71941 on December 3, 2002. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate

technological collection techniques or other forms of information technology.

**DATES:** Submit comments on or before March 24, 2003.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:**

Cecelia Davis, Acquisition Policy Division, GSA, (202) 219-0202.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

Under the North American Free Trade Agreement (NAFTA) Implementation Act, unless specifically exempted by statute or regulation, agencies are required to evaluate offers over a certain dollar limitation to supply an eligible product without regard to the restrictions of the Buy American Act or the Balance of Payments program. Offerors identify excluded end products and NAFTA end products on this certificate.

The contracting officer uses the information to identify the offered items which are domestic and NAFTA country end products so as to give these products a preference during the evaluation of offers. Items having components of unknown origin are considered to have been mined, produced, or manufactured outside the United States.

**B. Annual Reporting Burden**

*Respondents:* 1,140.

*Responses Per Respondent:* 5.

*Annual Responses:* 5,700.

*Hours Per Response:* .167.

*Total Burden Hours:* 952.

*Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (MVA), Room 4035, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0130, Buy American Act—North American Free Trade Agreement—Israeli Trade Act Certificate, in all correspondence.

Dated: February 11, 2003.

**Ralph J. Destefano,**

*Acting Director, Acquisition Policy Division.*

[FR Doc. 03-4102 Filed 2-19-03; 8:45 am]

**BILLING CODE 6820-EP-P**

**DEPARTMENT OF DEFENSE****Office of the Secretary****Meeting of the Advisory Panel To Assess the Capabilities for Domestic Response to Terrorist Attacks Involving Weapons of Mass Destruction**

**AGENCY:** Department of Defense.

**ACTION:** Notice of Meeting.

**SUMMARY:** this notice sets forth the schedule and summary agenda for the next meeting of the Panel to Assess the Capabilities for Domestic Response to Terrorist Attacks Involving Weapons of Mass Destruction. Notice of this meeting is required under the Federal Advisory Committee Act. (Pub. L. 92-463).

**DATES:** March 20-21, 2003,

**ADDRESSES:** RAND, 1200 S. Hayes Street, 4th floor, Arlington, VA 22202-5050. Mail written presentations and requests to register to attend the open public session to: Hillary Peck, RAND, 1200 South Hayes Street, Arlington, VA 22202-5050.

**FOR FURTHER INFORMATION CONTACT:** RAND provides information about this Panel on its web site at <http://www.rand.org/organization/nsrd/terrpanel/>; it can also be reached at (703) 413-1100 extension 5683.

**SUPPLEMENTARY INFORMATION:** Public comment presentations will be limited to two minutes each and must be provided in writing prior to the meeting. Public seating for this meeting is limited, and is available on a first-come, first-served basis.

**Proposed Schedule and Agenda**

Panel to Assess the Capabilities for Domestic Response to Terrorist Attacks Involving Weapons of Mass Destruction will meet from 9 a.m. until 5:30 p.m. on March 20, 2003 and from 8:30 a.m. until 3 p.m. on March 21, 2003. Time will be allocated for public comments by individuals or organizations at the end of the meeting on March 21.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4073 Filed 2-19-03; 8:45 am]

**BILLING CODE 5001-08-M**

**ACTION:** Notice of Advisory Committee meeting date change.

**SUMMARY:** On Friday, December 13, 2002 (67 FR 76728), the Department of Defense announced closed meetings of the Defense Science Board (DSB) Task Force on Seabasing. The meetings originally scheduled for February 25-26, 2003, have been changed to February 26-27, 2003. The meetings will be held at Strategic Analysis Inc., 3601 Wilson Boulevard, Suite 600, Arlington, VA.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4071 Filed 2-19-03; 8:45 am]

**BILLING CODE 5001-08-M**

**DEPARTMENT OF DEFENSE****Office of the Secretary****Defense Science Board**

**AGENCY:** Department of Defense.

**ACTION:** Notice of advisory committee meetings.

**SUMMARY:** The Defense Science Board Task Force on Unexploded Ordnance (UXO) will meet in closed session on April 22-23, 2003, and May 13-14, 2003, at SAIC Inc., 4001 N. Fairfax Street, Arlington, VA. This Task Force will review modern technology that can be exploited or developed to reduce the extremely high cost of UXO clean up.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on Scientific and Technical matters as they affect the perceived needs of the Department of Defense. At these meetings, the Defense Science Board Task Force will review and evaluate the Department's ability to exploit modern technology to reduce the extremely high cost of UXO clean up and improve its effectiveness for both contaminated land and water ranges and help accomplish the job in a reasonable time; and science and technologies that can be developed to support and sustain continued live fire training and testing of munitions at ranges across the United States with an acceptable environmental impact.

In accordance with Section 10(d) of the Federal Advisory Committee Act, P.L. No. 92-463, as amended (5 U.S.C. App. II), it has been determined that these Defense Science Board Task Force meetings concern matters listed in 5 U.S.C. 552b(b)(1) and that, accordingly,

these meetings will be closed to the public.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4072 Filed 2-19-03; 8:45 am]

**BILLING CODE 5001-08-M**

**DEPARTMENT OF DEFENSE****Office of the Secretary****Meeting of the DOD Advisory Group on Electron Devices**

**AGENCY:** Department of Defense, Advisory Group on Electron Devices.

**ACTION:** Notice.

**SUMMARY:** Working Group C (Electro-Optics) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting. The announcement of the meeting is being published in less than the 15 day requirement by law because of scheduling conflicts.

**DATE:** The meeting will be held at 0900, Wednesday, February 5, 2003.

**ADDRESSES:** The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

**FOR FURTHER INFORMATION CONTACT:** Elise Rabin, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

**SUPPLEMENTARY INFORMATION:** The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition, Technology and Logistics to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The Working Group C meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This opto-electronic device area includes such programs as imaging device, infrared detectors and lasers. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. No. 92-463, as amended, (5 U.S.C. App. § 10(d)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. § 552b(c)(1), and that

accordingly, this meeting will be closed to the public.

Dated: February 4, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03-4068 Filed 2-19-03; 8:45 am]

BILLING CODE 5001-08-M

## DEPARTMENT OF DEFENSE

### Defense Finance and Accounting Service

#### Privacy Act of 1974; System of Records

**AGENCY:** Defense Finance and Accounting Service, DoD.

**ACTION:** Notice of Altered System of Records.

**SUMMARY:** The Defense Finance and Accounting Service proposes to alter an existing system of records notice in its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The alteration consists of adding four routine uses to permit the release of information to:

The Army Emergency Relief, Navy-Marine Corps Relief Society, and Air Force Assistance Fund to process allotments for repayment of interest-free loans from the society and retiree charitable allotments in support of fund drives initiated by the Secretaries of the Army, Navy, and Air Force. The information will be used to process allotments on behalf of service members and retirees.

Officials and employees of the American Red Cross in the performance of their official duties relating to the assistance of the members and their dependents and relatives.

Former spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1450(f)(3), regarding Survivor Benefit Plan coverage.

Spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1448(a), regarding Survivor Benefit Plan coverage.

**DATES:** This action will be effective without further notice on March 24, 2003 unless comments are received that would result in a contrary determination.

**ADDRESSES:** FOIA/PA Program Manager, Defense Finance and Accounting Service—Denver Center, Specialized Legal Support Division, Office of General Counsel, 6760 E. Irvington Place, Denver, CO 80279-8000.

**FOR FURTHER INFORMATION CONTACT:** Ms. Linda Krabbenhoft on (303) 676-7514.

**SUPPLEMENTARY INFORMATION:** The complete inventory of Defense Finance and Accounting Service records system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on January 27, 2003, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

#### T7347b

##### SYSTEM NAME:

Defense Military Retiree and Annuity Pay System (April 12, 1999, 64 FR 17629).

##### CHANGES:

\* \* \* \* \*

##### SYSTEM LOCATION:

Delete entry and replace with "Defense Finance and Accounting Service—Cleveland, 1240 East Ninth Street, Cleveland, OH 44199-2055."

\* \* \* \* \*

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with "5 U.S.C. 301, Departmental Regulations; 10 U.S.C., Chapters 61, 63, 65, 67, 69, 71, 73, 74; Pub. L. 92-425; DoD Financial Management Regulation 7000.14-R, Volume 7B; and E.O. 9397 (SSN)."

\* \* \* \* \*

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete the fourth paragraph and replace with "Information is provided to individuals authorized to receive retired and annuitant payments on behalf of retirees or annuitants."

Add four new paragraphs to the entry. The Army Emergency Relief, Navy-Marine Corps Relief Society, and Air Force Assistance Fund to process allotments for repayment of interest-free

loans from the society and retiree charitable allotments in support of fund drives initiated by the Secretaries of the Army, Navy, and Air Force. The information will be used to process allotments on behalf of service members and retirees.

Officials and employees of the American Red Cross in the performance of their official duties relating to the assistance of the members and their dependents and relatives.

Former spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1450(f)(3), regarding Survivor Benefit Plan coverage.

Spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1448(a), regarding "Survivor Benefit Plan coverage."

\* \* \* \* \*

##### RETENTION AND DISPOSAL:

Delete entry and replace with "Disposition for Retired and Annuity Pay records range from 30 days to 56 years. The administrative records such as, change of address, electronic messages, or tax records, that are not pay affecting, are destroyed using a retention of 30 days to less than 6 years. All pay affecting documents such as retirement documents, account computation information, or entitlement/eligibility records are retained for six years or more, and the pay histories are retained for 56 years."

\* \* \* \* \*

#### T7347b

##### SYSTEM NAME:

Defense Military Retiree and Annuity Pay System.

##### SYSTEM LOCATION:

Defense Finance and Accounting Service—Cleveland, 1240 East Ninth Street, Cleveland, OH 44199-2055.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military retirees, their dependents, and their survivors. Categories of records in the system:

Military retiree and annuitant pay master files with supporting documentation relating to entitlements and deductions.

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C., Chapters 61, 63, 65, 67, 69, 71, 73, 74; Pub.L. 92-425; DoD Financial Management Regulation 7000.14-R, Volume 7B; and E.O. 9397 (SSN).

**PURPOSE(S):**

To maintain pay and personnel information for use in the computation of military retired pay and survivor annuity pay.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Records are provided to the Internal Revenue Service for normal wage and tax withholding.

Disclosures are made to the Department of Veterans Affairs (DVA) regarding establishments, changes and discontinuing of DVA compensation to retirees and annuitants.

Information is provided to individuals authorized to receive retired and annuitant payments on behalf of retirees or annuitants.

The Army Emergency Relief, Navy-Marine Corps Relief Society, and Air Force Assistance Fund to process allotments for repayment of interest-free loans from the society and retiree charitable allotments in support of fund drives initiated by the Secretaries of the Army, Navy, and Air Force. The information will be used to process allotments on behalf of service members and retirees.

Officials and employees of the American Red Cross in the performance of their official duties relating to the assistance of the members and their dependents and relatives.

Former spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1450(f)(3), regarding Survivor Benefit Plan coverage.

Spouses for purposes of providing information, consistent with the requirements of 10 U.S.C. 1448(a), regarding Survivor Benefit Plan coverage.

The DoD "Blanket Routine Uses" published at the beginning of the DFAS compilation of systems of records notices also apply to this system.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Maintained in file folders/notebooks/binder/visible file binders/cabinets/card files, computer magnetic tapes and paper printouts, on roll microfilm, microfiche, and optical disk.

**RETRIEVABILITY:**

Retrieved by name and Social Security Number of the retiree or annuitant.

**SAFEGUARDS:**

Records are maintained in a controlled facility. Physical entry is restricted by the use of locks, guards, and is accessible only to authorized personnel. Access to records is limited to person(s) responsible for servicing the record in performance of their official duties and who are properly screened and cleared for need-to-know. Access to computerized data is restricted by passwords, which are changed periodically.

**RETENTION AND DISPOSAL:**

Disposition for Retired and Annuitant Pay records range from 30 days to 56 years. The administrative records such as, change of address, electronic messages, or tax records, that are not pay affecting, are destroyed using a retention of 30 days to less than 6 years. All pay affecting documents such as retirement documents, account computation information, or entitlement/eligibility records are retained for six years or more, and the pay histories are retained for 56 years.

**SYSTEM MANAGER(S) AND ADDRESS:**

Policy official: Director of Continuing Government Activity, Defense Finance and Accounting Service—Cleveland, (DFAS-PD/CL), 1240 East Ninth Street, Cleveland, OH 44199-2055.

Record holder: Systems Manager, Affiliated Computer Systems, Defense Finance and Accounting Service—Cleveland, 1240 East Ninth Street, Cleveland OH 44199-2055.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves is contained in this record system should address written inquiries to the Privacy Act Officer, Defense Finance and Accounting Service—Cleveland, Office of General Counsel, (DFAS-GA/CL), 1240 East Ninth Street, Cleveland, OH 44199-8006.

The requester should be able to provide sufficient proof of identity, such as name, Social Security Number, place of employment, or other information available from the record itself.

**RECORD ACCESS PROCEDURES:**

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Privacy Act Officer, Defense Finance and Accounting Service—Cleveland, Office of General Counsel, (DFAS-GA/CL), 1240 East

Ninth Street, Cleveland, OH 44199-8006.

The requester should be able to provide sufficient proof of identity, such as name, Social Security Number, place of employment, or other information available from the record itself.

**CONTESTING RECORD PROCEDURES:**

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11-R; 32 CFR part 324; or may be obtained from the Privacy Act Officer at any DFAS Center.

**RECORD SOURCE CATEGORIES:**

From the individual concerned; financial, educational, and medical institutions; other DoD Components; state or local governments; and source documents such as reports. Members' survivors, members, guardians of survivors (children), private law firms which are executors of estates in casualty cases, and other government agencies such as the Department of Veterans Affairs and the Social Security Administration.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 03-4067 Filed 2-19-03; 8:45 am]

BILLING CODE 5001-08-P

**DEPARTMENT OF DEFENSE****Defense Information Systems Agency****Privacy Act of 1974; System of Records**

**AGENCY:** Defense Information Systems Agency, DoD.

**ACTION:** Notice to Delete Systems of Records.

**SUMMARY:** The Defense Information Systems Agency is deleting three systems of records notices from its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

**DATES:** This proposed action will be effective without further notice on March 24, 2003 unless comments are received which result in a contrary determination.

**ADDRESSES:** Send comments to the Defense Information Systems Agency, 5600 Columbia Pike, Room 933-I, Falls Church, VA 22041-2705.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Bosworth at (703) 681-2066.

**SUPPLEMENTARY INFORMATION:** The Defense Information Systems Agency systems of records notices subject to the

Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

#### KDCE.01

##### SYSTEM NAME:

Visit Notification/Clearance Verification Records NR501-11 (February 22, 1993, 58 FR 10562).

Reason: The notice was published to cover records being maintained at the DISA facility located in Reston, VA. The facility has since been vacated, therefore, records collected and maintained in this system of records were destroyed one year after facility was vacated.

#### KDCE.02

##### SYSTEM NAME:

Parking Permit Control Files 501-07 (February 22, 1993, 58 FR 10562).

Reason: The notice was published to cover records being maintained at the DISA facility located in Reston, VA. The facility has since been vacated, therefore, records collected and maintained in this system of records have been destroyed.

#### KDTI.01

##### SYSTEM NAME:

Permanent Change of Stations Records (August 22, 2000, 65 FR 50974).

Reason: This system of records was never activated. No records were ever collected or maintained under this system of records notice.

[FR Doc. 03-4065 Filed 2-19-03; 8:45 am]

BILLING CODE 5001-08-P

## DEPARTMENT OF DEFENSE

### Defense Logistics Agency

#### Privacy Act of 1974; Systems of Records

**AGENCY:** Defense Logistics Agency, DoD.

**ACTION:** Notice to Add a System of Records.

**SUMMARY:** The Defense Logistics Agency proposes to add a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**DATES:** This action will be effective without further notice on March 24, 2003 unless comments are received that would result in a contrary determination.

**ADDRESSES:** Send comments to the Privacy Act Officer, Headquarters, Defense Logistics Agency, ATTN: DSS-C, 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, VA 22060-6221.

**FOR FURTHER INFORMATION CONTACT:** Ms. Susan Salus at (703) 767-6183.

**SUPPLEMENTARY INFORMATION:** The Defense Logistics Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on January 27, 2003, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: February 12, 2003.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

#### S180.30 DSCR

##### SYSTEM NAME:

FOIA and Privacy Act Request Tracking System.

##### SYSTEM LOCATION:

Defense Supply Center Richmond, 8000 Jefferson Davis Highway, Richmond, VA 23297-5100.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed Freedom of Information Act (FOIA) or Privacy Act requests with the Defense Supply Center Richmond (DSCR).

##### CATEGORIES OF RECORDS IN THE SYSTEM:

The database includes name of requester, business or home address, business or home telephone and facsimile numbers, email address, pre-assigned Commercial and Government Entity code (if provided), a description of the records sought, and any

additional details voluntarily included in the text of the request. The database also includes machine-entered information such as case number, date of receipt, and suspense date and human entered information such as processing costs, closeout date, final action on request, and similar administrative details. Where personal information is sought, the database may also include Social Security Number for identification purposes. The database does not include copies of the requested records.

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552, Freedom of Information Act; 5 U.S.C. 552a, The Privacy Act of 1974, as amended; 10 U.S.C. 133, Under Secretary of Defense for Acquisition, Technology, and Logistics; and E.O. 9397 (SSN).

##### PURPOSE(S):

The records are maintained to administer the Freedom of Information and Privacy Act programs and to track requests received within DSCR. The files are also used to prepare annual and ad hoc reports.

Statistical data with all personal identifiers removed may be used by management for workload or manpower assessment and control.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD "Blanket Routine Uses" set forth at the beginning of DLA's compilation of systems of records notices apply to this system.

##### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

Records are stored electronically.

##### RETRIEVABILITY:

Records are retrieved by case number, individual's name, or business entity.

##### SAFEGUARDS:

Access to the database is limited to those who require the records in the performance of their official duties. Access is further restricted by the use of passwords which are changed periodically. Physical entry is restricted by the use of locks, guards, and administrative procedures. Employees are periodically briefed on the

consequences of improperly accessing restricted databases.

#### RETENTION AND DISPOSAL:

Cases involving full and partial denials; fee waiver, requester category, and expedited treatment denials; or other adverse determinations are maintained for 6 years. Cases involving full releases or administrative dispositions (such as transfers to other agencies; withdrawals by requester; inadequate descriptions; failure to pay fees; or other instances of noncompliance on the requester's part) are maintained for 2 years.

#### SYSTEM MANAGER(S) AND ADDRESS:

Freedom of Information/Privacy Act Officer, Defense Supply Center Richmond, ATTN: DSCR-SP, 8000 Jefferson Davis Highway, Richmond, VA 23297-5100.

#### NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Privacy Act Officer, Defense Supply Center Richmond, ATTN: SP, 8000 Jefferson Davis Highway, Richmond, VA 23297-5100.

Written requests should contain the full name and current address, telephone number of the individual, and approximate time frame involved.

#### RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Privacy Act Officer, Defense Supply Center Richmond, ATTN: DSCR-SP, 8000 Jefferson Davis Highway, Richmond, VA 23297-5100.

Written requests should contain the full name, current address, and telephone number of the individual. Depending on the nature of the records involved, requesters may be asked to supply Social Security Number and a notarized statement or a signed and dated unsworn declaration (in accordance with 28 U.S.C. 1746) stating under penalty of perjury that the information contained in the request for access, including their identity, is true and correct.

#### CONTESTING RECORD PROCEDURES:

The DLA rules for accessing records, for contesting contents and appealing initial agency determinations are contained in DLA Regulation 5400.21, 32 CFR part 323, or may be obtained from the Privacy Act Officer, Headquarters, Defense Logistics Agency,

ATTN: DSS-C, 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, VA 22060-6221.

#### RECORD SOURCE CATEGORIES:

Data is provided by the record subject, the FOIA/Privacy Act staff, and program software.

#### EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 03-4066 Filed 2-19-03; 8:45 am]

BILLING CODE 5001-08-P

## DEPARTMENT OF DEFENSE

### Corps of Engineers, Department of the Army

#### Transfer of jurisdiction of a portion of Joliet Army Ammunition Plant to the Department of Agriculture for the Midewin National Tallgrass Prairie

AGENCY: Army Corps of Engineers, DOD.

ACTION: Notice.

**SUMMARY:** On October 25, 2002, in accordance with PL 104-106, Title XXIX, Subtitle A, entitled "Illinois Land Conservation Act of 1995", the Department of the Army signed a Secretariat Memorandum to transfer approximately 10.5 acres of land at Joliet Army Ammunition Plant, Illinois to the Department of Agriculture for use by the Forest Service as the Midewin National Tallgrass Prairie. The purpose of this notice is to effect that transfer pursuant to the provisions of section 2912 (e)(2) of Pub. L. 104-106.

This is a partial transfer of the entire acreage contemplated by the statute. Additional transfers will be made in the future. A legal description dated March 6, 2001 of the property, which is the subject of the partial transfer, is on file with the U.S. Army Engineer District, Corps of Engineers, Louisville, Kentucky and the Office of the Regional Forester, USDA, Forest Service.

**FOR FURTHER INFORMATION CONTACT:** Mr. Lloyd A. Foe, 502-315-6969.

**ADDRESSES:** Documents are on file at locations:

1. U.S. Army Engineer District, Louisville, Corps of Engineers, PO Box 59, Louisville, Kentucky 40201-0059.
2. Office of the Regional Forester, USDA, Forest Service, 310 W. Wisconsin Avenue, Milwaukee, Wisconsin 53203.

**SUPPLEMENTARY INFORMATION:** None.

**Michael G. Barter,**  
Chief, Real Estate Division.

[FR Doc. 03-4024 Filed 2-19-03; 8:45 am]

BILLING CODE 3710-JB-P

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before April 21, 2003.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.



Dated: February 13, 2003.

**John D. Tressler,**

*Leader, Regulatory Management Group,  
Office of the Chief Information Officer.*

#### Office of Postsecondary Education

*Type of Review:* Revision of a currently approved collection.

*Title:* High Education Act (HEA) Title II Reporting Forms on Teacher Quality and Preparation.

*Frequency:* Annually.

*Affected Public:* State, Local, or Tribal Gov't, SEAs or LEAs (primary). Not-for-profit institutions (primary).

*Reporting and Recordkeeping Hour Burden:* Responses: 1309. Burden Hours: 127624.

*Abstract:* The Higher Education Act of 1998 calls for annual reports from states and institutions of higher education on the quality of teacher education and related matters (Pub. L. 105-244, section 207:20 U.S.C. 1027). The purpose of the reports is to provide greater accountability in the preparation of America's teaching forces and to provide information and incentives for its improvement. Most institutions of higher education that have teacher preparation programs must report annually to their states on the performance of their program completers on teacher certification tests. States, in turn, must report test performance information, institution by institution, to the Secretary of Education, along with institutional ranking. They must also report on their requirements for licensing teachers, state standards, alternative routes to certification, waivers, and related items. Annually reports from institutions are due to the states, beginning April 7 each year; reports from the states are due annually to the Secretary, beginning October 7 each year; the Secretary's report is due annually to Congress, beginning April 7 each year. These dates are one year later than the dates in the legislation.

Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address [Vivian.reese@ed.gov](mailto:Vivian.reese@ed.gov). Requests may also be faxed to (202) 708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at his e-mail address [Joe.Schubart@ed.gov](mailto:Joe.Schubart@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 03-4050 Filed 2-19-03; 8:45 am]

BILLING CODE 4000-01-P

#### DEPARTMENT OF EDUCATION

##### Submission for OMB Review; Comment Request

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Management Group, Office of the Chief

Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before March 24, 2003.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the Internet address [Lauren.Wittenberg@omb.eop.gov](mailto:Lauren.Wittenberg@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: February 13, 2003.

**John D. Tressler,**

*Leader, Regulatory Management Group,  
Office of the Chief Information Officer.*

#### Office of Postsecondary Education

*Type of Review:* Extension of a currently approved collection.

*Title:* Scholarship Contract & Teaching Verification Form for Title II HEA Scholarship Recipients (JS).

*Frequency:* On Occasion Semi-Annually Annually.

*Affected Public:* Individuals or household (primary). Not-for-profit institutions. State, Local, or Tribal Gov't, SEAs or LEAs.

*Reporting and Recordkeeping Hour Burden:* Responses: 4450. Burden Hours: 3250.

*Abstract:* Students receiving scholarships under section 204(3) of the Higher Education Act incur a service obligation to teach in a high-need school in a high-need LEA. This information collection consists of: (1) a contract to be executed when funds are first awarded; (2) an addendum to the contract to be signed when subsequent funds are awarded; (3) a teaching verification form to be used by students to document their compliance with the contract's conditions.

Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or directed to her e-mail address [Vivian.Reese@ed.gov](mailto:Vivian.Reese@ed.gov). Requests may also be faxed to (202) 708-9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at his e-mail address [Joe.Schubart@ed.gov](mailto:Joe.Schubart@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 03-4049 Filed 2-19-03; 8:45 am]

BILLING CODE 4000-01-P

#### DEPARTMENT OF EDUCATION

##### Alabama Department of Education; Written Findings and Compliance Agreement

**AGENCY:** Office of Elementary and Secondary Education, Department of Education.

**ACTION:** Notice of written findings and compliance agreement.

**SUMMARY:** Section 457 of the General Education Provisions Act (GEPA) authorizes the U.S. Department of Education to enter into a compliance agreement with a recipient that is failing to comply substantially with Federal program requirements. In order to enter into a compliance agreement, the Department must determine, in written findings, that the recipient cannot comply until a future date with the applicable program requirements and that a compliance agreement is a viable means of bringing about such compliance. On March 27, 2002, the Assistant Secretary for Elementary and Secondary Education (Assistant Secretary) entered into a compliance agreement with the Alabama Department of Education (ALDE). Under section 457(b)(2) of GEPA, the written findings and compliance agreement must be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Dr. Grace A. Ross, U.S. Department of



Education, Office of Elementary and Secondary Education, 400 Maryland Avenue, SW., room 3W118, Washington, DC 20202. Telephone: (202) 260-0967.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

**SUPPLEMENTARY INFORMATION:** Under title I, part A of the Elementary and Secondary Education Act of 1965 (title I), each State, including the District of Columbia and Puerto Rico, was required to develop or adopt, by the 1997-98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do. Each State also was required to develop or adopt performance standards, aligned with its content standards, which describe three levels of proficiency to determine how well students are mastering the content standards. Finally, by the 2000-2001 school year, each State was required to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools in enabling students to meet the State's performance standards.

The Alabama Department of Education (ALDE) submitted, and the Department approved, evidence that it has content standards in at least reading/language arts and mathematics. In October 2000, ALDE submitted evidence of its final assessment system. The Department submitted that evidence to a panel of three assessment experts for peer review and following that review the Acting Assistant Secretary determined that Alabama must enter a compliance agreement with the Department. The ALDE submitted additional information and this evidence was peer reviewed in August 2001. Following that review, the Assistant Secretary for Elementary and Secondary Education concluded that ALDE's proposed final assessment system and performance standards did not meet a number of the Title I requirements.

Section 454 of GEPA, 20 U.S.C. 1234c, sets out the remedies available to the Department when it determines that a recipient "is failing to comply

substantially with any requirement of law" applicable to Federal program funds the Department administers. Specifically, the Department is authorized to—

- (1) Withhold funds;
- (2) Obtain compliance through a cease and desist order;
- (3) Enter into a compliance agreement with the recipient; or
- (4) Take any other action authorized by law. 20 U.S.C. 1234c(a)(1) through (a)(4).

In a letter dated November 19, 2001, to Dr. Edward R. Richardson, Superintendent of Schools for the Alabama Department of Education, the Assistant Secretary notified ALDE that, in order to remain eligible to receive Title I funds, it must enter into a compliance agreement with the Department. The purpose of a compliance agreement is "to bring the recipient into full compliance with the applicable requirements of law as soon as feasible and not to excuse or remedy past violations of such requirements." 20 U.S.C. 1234f(a). In order to enter into a compliance agreement with a recipient, the Department must determine, in written findings, that the recipient cannot comply until a future date with the applicable program requirements, and that a compliance agreement is a viable means for bringing about such compliance.

On April 8, 2002, the Assistant Secretary issued written findings, holding that compliance by ALDE with the title I standards and assessment requirements is genuinely not feasible until a future date. Having first submitted its assessment system for peer review in October 2000, ALDE was not able to make the significant changes to its system that the Department's peer review required in time to meet the spring 2001 statutory deadline to have approved assessments in place. As a result, ALDE administered its unapproved assessment system in 2001. The Assistant Secretary also determined that a compliance agreement represents a viable means of bringing about compliance because of the steps ALDE has already taken to comply, its commitment of resources, and the plan it has developed for further action. The agreement sets out the action plan that ALDE must meet to come into compliance with the title I requirements. This plan, coupled with specific reporting requirements, will allow the Assistant Secretary to monitor closely ALDE's progress in meeting the terms of the compliance agreement. Both the Superintendent of ALDE, Dr. Edward R. Richardson, and the

Assistant Secretary signed the agreement on March 27, 2002.

As required by section 457(b)(2) of GEPA, 20 U.S.C. 1234f(b)(2), the text of the Assistant Secretary's written findings is set forth as appendix A and the compliance agreement is set forth as appendix B of this notice.

#### **Electronic Access to This Document**

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(Authority: 20 U.S.C. 1234c, 1234f, 6311)

Dated: February 13, 2003.

**Eugene W. Hickock,**  
*Under Secretary of Education.*

#### **Appendix A—Text of the Written Findings of the Assistant Secretary for Elementary and Secondary Education**

##### *I. Introduction*

The Assistant Secretary for Elementary and Secondary Education (Assistant Secretary) of the U.S. Department of Education (Department) has determined, pursuant to 20 U.S.C. 1234c and 1234f, that the Alabama Department of Education (ALDE) has failed to comply substantially with certain requirements of title I, part A of the Elementary and Secondary Education Act of 1965 (title I), 20 U.S.C. 6301 *et seq.*, and that it is not feasible for ALDE to achieve full compliance immediately. Specifically, the Assistant Secretary has determined that ALDE failed to meet a number of the title I requirements concerning the development of performance standards and an aligned assessment system within the statutory timeframe.

For the following reasons, the Assistant Secretary has concluded that it would be appropriate to enter into a compliance agreement with ALDE to bring it into full compliance as soon as feasible. During the effective period of the compliance agreement, which ends three years from the date of these

findings, ALDE will be eligible to receive title I funds as long as it complies with the terms and conditions of the agreement as well as the provisions of title I, part A and other applicable Federal statutory and regulatory requirements.

## II. Relevant Statutory and Regulatory Provisions

### A. Title I, Part A of the Elementary and Secondary Education Act of 1965

Title I, part A of the Elementary and Secondary Education Act of 1965 (title I), 20 U.S.C. 6301 *et seq.*, provides financial assistance, through State educational agencies, to local educational agencies to provide services in high-poverty schools to students who are failing or at risk of failing to meet the State's student performance standards. Under title I, each State, including the District of Columbia and Puerto Rico, was required to develop or adopt, by the 1997–98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do and performance standards, aligned with those content standards, that describe three levels of proficiency to determine how well students are mastering the content standards.

By the 2000–2001 school year, title I required each State to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools and school districts in enabling students to meet the State's performance standards. These assessments must meet the following requirements:

- The assessments must be aligned to a State's content and performance standards.
- They must be administered annually to students in at least one grade in each of three grade ranges: grades 3 through 5, grades 6 through 9, and grades 10 through 12.
- They must be valid and reliable for the purpose for which they are used and of high technical quality.
- They must involve multiple measures, including measures that assess higher-order thinking skills.
- They must provide for the inclusion of all students in the grades assessed, including students with disabilities and limited English proficient students.
- They must provide individual reports on the students tested.
- Results from the assessments must be disaggregated and reported by major racial and ethnic groups and other categories.

- 20 U.S.C. 6311(b)(3).<sup>1</sup>

### B. The General Education Provisions Act

The General Education Provisions Act (GEPA) provides a number of options when the Assistant Secretary determines a recipient of Department funds is "failing to comply substantially with any requirement of law applicable to such funds." 20 U.S.C. 1234c. In such case, the Assistant Secretary is authorized to—

- (1) Withhold funds;
- (2) Obtain compliance through a cease and desist order;
- (3) Enter into a compliance agreement with the recipient; or
- (4) Take any other action authorized by law. 20 U.S.C. 1234c(a)(1) through (a)(4).

Under section 457 of GEPA, the Assistant Secretary may enter into a compliance agreement with a recipient that is failing to comply substantially with specific program requirements. 20 U.S.C. 1234f. The purpose of a compliance agreement is "to bring the recipient into full compliance with the applicable requirements of the law as soon as feasible and not to excuse or remedy past violations of such requirements." 20 U.S.C. 1234f(a). Before entering into a compliance agreement with a recipient, the Assistant Secretary must hold a hearing at which the recipient, affected students and parents or their representatives, and other interested parties are invited to participate. At that hearing, the recipient has the burden of persuading the Assistant Secretary that full compliance with the applicable requirements of law is not feasible until a future date and that a compliance agreement is a viable means for bringing about such compliance. 20 U.S.C. 1234f(b)(1). If, on the basis of all the available evidence, the Assistant Secretary determines that compliance

until a future date is genuinely not feasible and that a compliance agreement is a viable means for bringing about such compliance, the Assistant Secretary must make written findings to that effect and publish those findings, together with the substance of any compliance agreement, in the **Federal Register**. 20 U.S.C. 1234f(b)(2).

A compliance agreement must set forth an expiration date, not later than three years from the date of these written findings, by which time the recipient must be in full compliance with all program requirements. 20 U.S.C. 1234f(c)(1). In addition, a compliance agreement must contain the terms and conditions with which the recipient must comply during the period that agreement is in effect. 20 U.S.C. 1234f(c)(2). If the recipient fails to comply with any of the terms and conditions of the compliance agreement, the Assistant Secretary may consider the agreement no longer in effect and may take any of the compliance actions described previously. 20 U.S.C. 1234f(d).

## III. Analysis

### A. Overview of Issues To Be Resolved in Determining Whether a Compliance Agreement Is Appropriate

In deciding whether a compliance agreement between the Assistant Secretary and ALDE is appropriate, the Assistant Secretary must first determine whether compliance by ALDE with the title I standards and assessment requirements is genuinely not feasible until a future date. 20 U.S.C. 1234f(b). The second issue that the Assistant Secretary must resolve is whether ALDE will be able, within a period of up to three years, to come into compliance with the title I requirements. Not only must ALDE come into full compliance by the end of the effective period of the compliance agreement, it must also make steady and measurable progress toward that objective while the compliance agreement is in effect. If such an outcome is not possible, then a compliance agreement between the Assistant Secretary and ALDE would not be appropriate.

### B. ALDE Has Failed To Comply Substantially With Title I Standards and Assessment Requirements

In October 2000, ALDE submitted evidence of its final assessment system. The Assistant Secretary submitted that evidence to a panel of three assessment experts for peer review. Alabama submitted additional information and this evidence was peer reviewed in August 2001. Following that review, the

<sup>1</sup> On January 8, 2002, title I of the Elementary and Secondary Education Act was reauthorized by the No Child Left Behind Act of 2001 (NCLB) (Pub. L. 107–110). The NCLB made several significant changes to the Title I standards and assessment requirements. First, it requires that each State develop academic content and student achievement standards in science by the 2005–06 school year. Second, by the 2005–06 school year, it requires a system of aligned assessments in each of grades 3 through 8 and once during grades 10 through 12. Third, it requires science assessments in at least three grade spans by the 2007–08 school year. Fourth, the NCLB significantly changes the definition of adequate yearly progress each State must establish to hold schools and school districts accountable, based on data from the 2001–02 test administration. Finally, by the 2002–03 school year, the NCLB requires State and school district report cards that include, among other things, assessment results disaggregated by various subgroups, two-year trend data, and percent of students tested.

Assistant Secretary for Elementary and Secondary Education concluded that ALDE's proposed final assessment system did not meet a number of the title I requirements. Specifically, the Assistant Secretary determined that ALDE must do the following:

- Develop or select an academic assessment system that represents the full range of the ALDE's academic content standards and academic achievement standards in at least reading/language arts and mathematics and is consistent with the title I requirements for use of multiple measures of student achievement, including measures that assess higher-order thinking and understanding. Document the alignment of the assessment system with ALDE's academic content and student achievement standards.

- Provide evidence that the State assessment shall be used for purposes for which such assessments are valid and reliable, and be consistent with relevant, nationally recognized professional and technical standards for such assessments.

- Provide evidence supporting the proposed Alabama Student Assessment Program that includes information on the financial capacity of Alabama to complete this system so that it meets the requirements of title I, including performance standards, alignment, technical quality, inclusion of all students, reporting, and use in the State's accountability system.

- Provide evidence of performance standards having three performance levels, with cut scores for all components of the assessment system, and the process to be used to determine that these performance standards are aligned with content standards and performance descriptors for all components of the assessment system incorporated into the State's accountability system.

- Provide evidence of participation rates for each grade assessed, each subject (reading and math), and, for students with disabilities (SWD) and limited English proficiency (LEP) populations, the total enrollment, number assessed, and number exempted. The number assessed should be broken down by types of assessment accommodation (regular, standard accommodations, non-standard accommodations, and alternate) for all components of the State assessment system that are included in the accountability system.

- Provide evidence of an approved comprehensive policy on assessment guidelines and accommodations for LEP students, clear guidance to LEAs and

schools related to the use of language proficiency tests for the LEP team decisions on accommodations for assessments, and a plan for implementing the new LEP inclusion policies and for monitoring LEA compliance with those policies.

- Provide evidence on the process used to incorporate data for SWD and LEP students into the assessment and accountability systems.

- Provide evidence regarding the extent to which all components of the Alabama assessment program contribute to the alignment of the content and performance standards; a description of the State's approach for ensuring alignment; and information on the cognitive complexity of all of the Alabama assessments.

- Provide evidence of a technical manual for the writing component and technical information on all the proposed components when they are available.

- Provide evidence to show how Alabama will disaggregate its performance data in grade spans 3–5 and 6–9 by economically disadvantaged students versus non-economically disadvantaged, race/ethnicity, and LEP status at the State, LEA, and school levels and on how Alabama will disaggregate its performance data by all the required categories at the high school level.

- Provide evidence on how ALDE will provide individual student reports and State, LEA, and school profiles by student performance standards and how it will report and disseminate student performance information to the necessary stakeholders at the LEA and school levels.

#### C. ALDE Cannot Correct Immediately Its Noncompliance With the Title I Standards and Assessment Requirements

Under the title I statute, ALDE was required to implement its final assessment system no later than the 2000–2001 school year. 20 U.S.C. 6311(b)(6). ALDE submitted evidence of its assessment system in October 2000 and August 2001 but the Assistant Secretary determined, on the basis of that evidence, that ALDE's system did not fully meet the title I requirements. Due to the enormity and complexity of developing a new assessment system that addressed the Assistant Secretary's concerns, ALDE was not able to complete that task between the time it first submitted its system for review and the spring 2001 assessment window. Thus, in spring 2001, ALDE administered the assessment that the Assistant Secretary had determined did

not meet the title I requirements. As a result, the Assistant Secretary finds that it is not genuinely feasible for ALDE to come into compliance until a future date.

#### D. ALDE Can Meet the Terms and Conditions of a Compliance Agreement and Come into Full Compliance With the Requirements of Title I Within Three years

At the public hearing, ALDE presented evidence of its commitment and capability to come into compliance with the title I standards and assessment requirements within three years. For example, Alabama successfully amended a law in 2000 that required the State Board of Education to implement a nationally normed test to assist in the assessment of student achievement in grades three through 11. Since that time, the State has been busy designing a new accountability system and adopting a new assessment plan for its schools, one that maintains high standards and comports with Federal law.

Finally, ALDE has developed a comprehensive action plan, incorporated into the compliance agreement, that sets out a very specific schedule that ALDE has agreed to meet during the next three years for attaining compliance with the title I standards and assessment requirements. As a result, ALDE is committed not only to coming into full compliance within three years, but to meeting a stringent, but reasonable, schedule for doing so. The action plan also demonstrates that ALDE will be well on its way to meeting the new standards and assessment requirements of the No Child Left Behind Act of 2001. The compliance agreement also sets out documentation and reporting procedures that ALDE must follow. These provisions will allow the Assistant Secretary to ascertain promptly whether ALDE is meeting each of its commitments under the compliance agreement and is on schedule to achieve full compliance within the effective period of the agreement.

The task of developing an assessment system that meets the title I requirements is not a quick or easy one. However, the Assistant Secretary has determined that, given the commitment of ALDE to comply with the terms and conditions of the compliance agreement, it is possible for ALDE to come into full compliance with the title I standards and assessment requirements within three years.

#### IV. Conclusion

For the foregoing reasons, the Assistant Secretary finds the following:

(1) That full compliance by ALDE with the standards and assessment requirements of title I is not feasible until a future date; and (2) that ALDE can meet the terms and conditions of the attached compliance agreement and come into full compliance with the title I standards and assessment requirements within three years of the date of these findings. Therefore, the Assistant Secretary has determined that it is appropriate to enter into a compliance agreement with ALDE. Under the terms of 20 U.S.C. 1234f, that compliance agreement becomes effective on the date of these findings.

Dated: March 27, 2002.

**Susan B. Neuman,**

*Assistant Secretary, Office of Elementary and Secondary Education.*

## **Appendix B—Text of the Compliance Agreement**

### **Compliance Agreement Under Title I of the Elementary and Secondary Education Act Between the United States Department of Education and the Alabama Department of Education**

#### *Introduction*

Title I of the Elementary and Secondary Education Act of 1965 (title I) required each State, including the District of Columbia and Puerto Rico, to develop or adopt, by the 1997–98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do. Title I also required each State to develop or adopt performance standards, aligned with those content standards, that describe three levels of proficiency to determine how well students are mastering the content standards. By the 2000–2001 school year, title I required each State to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools and school districts in enabling students to meet the State's performance standards.

The Alabama Department of Education (ALDE) was not able to meet these requirements by the statutory deadlines. In order to be eligible to continue to receive title I funds while working to comply with the statutory requirements, Dr. Edward R. Richardson, Superintendent of ALDE, indicated ALDE's interest in entering into a compliance agreement with the Office of Elementary and Secondary Education (OESE) of the United States Department of Education. On January 31, 2002, OESE conducted a public

hearing regarding ALDE's ability to come into compliance with the title I standards and assessment requirements within three years. Based on testimony at that hearing, Dr. Joseph Morton, Deputy State Superintendent, determined that "Alabama was one of the states that did not meet the deadline for title I compliance with all rules and regulations." The Deputy State Superintendent stated, "I am here today to testify that it can be done within a three-year span from the date of initiation of a signed compliance agreement." The Deputy State Superintendent's written findings are attached to, and incorporated by reference into, this Agreement.

Pursuant to this Compliance Agreement under 20 U.S.C. 1234f, ALDE must be in full compliance with the requirements of title I no later than three years from the date of the Assistant Secretary's written findings, a copy of which is attached to, and incorporated by reference into, this Agreement. Specifically, ALDE must meet, and document that it has met, the following requirements:

1. Develop or select an academic assessment system that represents the full range of ALDE's academic content standards and academic achievement standards in at least reading/language arts and mathematics and is consistent with the title I requirements for use of multiple measures of student achievement, including measures that assess higher-order thinking and understanding. Document the alignment of the assessment system with ALDE's academic content and student achievement standards.

2. Provide evidence that the State assessment shall be used for purposes for which such assessments are valid and reliable, and be consistent with relevant, nationally recognized professional and technical standards for such assessments.

3. Provide evidence supporting the proposed Alabama Student Assessment Program that includes information on the financial capacity of Alabama to complete this system so that it meets the requirements of title I, including performance standards, alignment, technical quality, inclusion of all students, reporting, and use in the State's accountability system.

4. Provide evidence of performance standards having three performance levels, with cut scores for all components of the assessment system, and the process to be used to determine that these performance standards are aligned with content standards and performance descriptors for all components of the assessment system

incorporated into your State's accountability system.

5. Provide evidence of participation rates for each grade assessed, each subject (reading and math), and, for SWD and LEP populations, the total enrollment, number assessed, and number exempted. The number assessed should be broken down by types of assessment accommodation (regular, standard accommodations, non-standard accommodations, and alternate) for all components of the State assessment system that you included in the accountability system.

6. Provide evidence of an approved comprehensive policy on assessment guidelines and accommodations for LEP students, clear guidance to LEAs and schools related to the use of language proficiency tests for the LEP team decisions on accommodations for assessments, and a plan for implementing the new LEP inclusion policies and for monitoring LEA compliance with those policies.

7. Provide evidence on the process used to incorporate data for SWD and LEP students into the assessment and accountability systems.

8. Provide evidence regarding the extent to which all components of the Alabama assessment program contribute to the alignment of the content and performance standards, a description of your State's approach for ensuring alignment; and information on the cognitive complexity of all of the Alabama assessments.

9. Provide evidence of a technical manual for the writing component and technical information on all the proposed components when they are available.

10. Provide evidence to show how Alabama will disaggregate its performance data in grade spans 3–5 and 6–9 by economically disadvantaged students versus non-economically disadvantaged, race/ethnicity, and LEP status at the State, LEA, and school levels and on how Alabama will disaggregate its performance data by all the required categories at the high school level.

11. Provide evidence on how your agency will provide individual student reports and State, LEA, and school profiles by student performance standards and how it will report and disseminate student performance information to the necessary stakeholders at the LEA and school levels.

During the period that this Compliance Agreement is in effect, ALDE is eligible to receive title I, part A funds if it complies with the terms and conditions of this Agreement, as

well as the provisions of title I, part A and other applicable Federal statutory and regulatory requirements. Specifically, the Compliance Agreement sets forth action steps ALDE must meet to come into compliance with the title I standards and assessment requirements. ALDE must submit documentation concerning its compliance with these action steps.

The action steps incorporated into this Compliance Agreement may be amended by joint agreement of the parties, provided full compliance can still be accomplished by the expiration date of the Agreement.

In addition to all of the terms and conditions set forth above, ALDE agrees

that its continued eligibility to receive title I, part A funds is predicated upon compliance with statutory and regulatory requirements of that program that have not been addressed by this Agreement, including the requirements of the No Child Left Behind Act of 2001.

If ALDE fails to comply with any of the terms and conditions of this Compliance Agreement, including the action steps, the Department may consider the Agreement no longer in effect and may take any action authorized by law, including the withholding of funds or the issuance of a cease and desist order. 20 U.S.C. § 1234f(d).

For the Alabama Department of Education:

Dated: March 27, 2002.

**Edward R. Richardson,**  
*State Superintendent of Schools.*

For the United States Department of Education:

Dated: March 27, 2002.

**Susan B. Neuman,**  
*Assistant Secretary, Office of Elementary and Secondary Education.*

Date this compliance agreement becomes effective: April 8, 2002.

Expiration date of this agreement: April 8, 2005.

**BILLING CODE 4000-01-P**

3/28/02

STATE OF ALABAMA  
ACTION PLAN FOR TITLE I COMPLIANCE AGREEMENT

Action Steps	Completion/ Submission Date to USDOE	Responsible Office	Documentation
Financial Capacity:			
1. Pursue funding through state legislature to support assessment and accountability system.	9-30-01	State Superintendent	FY2002 budget
2. Pursue increased funding for FY2003 to support proposed changes in the assessment and accountability system through state legislature currently in session.	9-30-02	State Superintendent	FY2003 budget
Assessment (IASA Sec. 1111(b):			
1. Send copy of RFP requesting services for CRT (augmented NRT) test development and administration to U.S. Department of Education.	4-30-02	Student Assessment	Copy of RFP Addendum to RFP

2. Release RFP for test development and administration of Alabama Direct Assessment of Writing: Grade Ten.	4-30-02	Student Assessment	Copy of RFP
3. Negotiate agreement with vendor for services to develop and administer Alabama Direct Assessment of Writing: Grade Ten.	7-31-02	Student Assessment	Purchase order
4. Meet with vendor to plan the design and implementation of development and pilot of Alabama Direct Assessment of Writing: Grade Ten.	7-31-02	Student Assessment	Minutes of planning meeting
5. Select norm-referenced test (NRT) in Grades 3-8 that allows augmentation in reading/language arts and mathematics in order to ensure alignment with Alabama content standards, resulting in CRT (augmented NRT).*	9-30-02	Student Assessment	Recommendation of Test Selection Committee and Technical Advisory Committee (4-member, external advisory group of university professors with expertise in research/measurement and education of students of special populations)

			State Board of Education resolution
6. Negotiate agreement with vendor for services to administer NRT, augment NRT, pilot CRT (augmented NRT), and administer CRT (augmented NRT).	9-30-02	Student Assessment	Purchase order
7. Meet with vendor to plan the design and implementation of NRT (including validity, reliability, and bias studies).	10-31-02	Student Assessment	Minutes of planning meeting
8. Develop and pilot Alabama Direct Assessment of Writing: Grade Ten with appropriate accommodations for students with disabilities and LEP.	2-28-03	Student Assessment	Test blueprint Testing schedule Test administration manual
9. Customization of NRT by augmenting test items in Grades 3-8 in order to (1) ensure alignment with Alabama's content standards	8-31-03	Student Assessment	Documentation of alignment of customized NRT to Alabama's content standards



resulting in CRT (augmented NRT), and (2) include measures of higher order thinking skills and understanding.*				Test blueprint
10. Pilot CRT (augmented NRT) in Grades 3-8 with appropriate accommodations for students with disabilities and LEP.*	11-30-03	Student Assessment		Testing schedule Test administration manual
Content Standards (IASA Sec. 1111(b)(1)(D)(i) :				
1. Document involvement of a broad base of stakeholders in the revision of content standards.	8-31-02	Curriculum Development		List of committee members
2. Review, revise, and adopt Alabama's content standards in language arts.	10-31-02	Curriculum Development		Description of process followed State Board of Education resolution Copy of revised content standards
3. Review, revise, and adopt Alabama's content	2-28-03	Curriculum Development		Description of process followed

standards in mathematics.			State Board of Education resolution Copy of revised content standards
Academic Achievement Standards (IASA Sec. 1111(b)(1):			
1. Review and revise Alabama's labels for academic achievement standards.	7-31-02	Student Assessment	Recommendation of Test Advisory Committee State Board of Education resolution
2. Document involvement of a broad base of stakeholders in the development of the academic achievement standards for the Alabama Alternate Assessment (AAA).	7-31-02	Student Assessment and Special Education	List of committee members
3. Standard setting to establish academic achievement standards for the AAA.	7-31-02	Student Assessment and Special Education	Description of process followed Report of results of standard setting
4. Document involvement of a broad base of	2-28-03	Student Assessment and	List of committee members

stakeholders in the development of the working draft of academic achievement standards descriptors and exemplars for the CRT (augmented NRT).		Curriculum Development	
5. Working draft of academic achievement standards descriptors and exemplars to be used in development of CRT (augmented NRT).	2-28-03	Student Assessment and Curriculum Development	Copy of working draft of academic achievement standards descriptors and exemplars
6. Document involvement of a broad base of stakeholders in the development of the academic achievement standards for the Alabama Occupational Portfolio Assessment (AOPA).	7-31-03	Student Assessment and Special Education	List of committee members
7. Standard setting to establish academic achievement standards for the AOPA.	7-31-03	Student Assessment and Special Education	Description of process followed Report of results of standard setting
8. Document involvement of	7-31-04	Student	List of committee members

a broad base of stakeholders in the standard setting process (descriptors, exemplars, and cut scores) for the CRT (augmented NRT) and the <i>Alabama High School Graduation Exam</i> (AHSGE).		Assessment	
9. Standard setting to establish academic achievement standards including final descriptors, exemplars, and cut scores for CRT (augmented NRT)* and AHSGE (addition of advanced level).	7-31-04	Student Assessment	Description of process followed Report of results of standard settings State Board of Education resolution
Content, Grade Levels, and Administration (IASA Sec. 1111(b) (3) (A) (D) (E) :			
1. Adoption of Proposed Alabama Student Assessment Program to include multiple measures which assess higher-order thinking skills and understanding to be administered annually to all students in the designated grades and content areas.	7-31-02	Student Assessment	Recommendation of Test Advisory Committee (principles and assessments) State Board of Education resolution.

2. Administer new NRT in Grades 3-8 (transitional assessments) that will be used for accountability purposes for the spring 2003.	4-30-03	Student Assessment	Testing schedule
3. Administer Alabama Direct Assessment of Writing: Grade Ten.	2-28-04	Student Assessment	Testing schedule Test administration manual
4. Administer CRT (augmented NRT) in Grades 3-8.*	4-30-04	Student Assessment	Testing schedule Test administration manual

## Inclusion (IASA Sec. 1111(b)(3)(A)(F):

1. Administer Alabama Alternate Assessment (AAA) [assessment for special education students in Grades K-12 who cannot participate in the regular state assessments] and develop and pilot Alabama Occupational Portfolio Assessment (AOPA) [assessment for special education students in	4-30-02	Student Assessment and Special Education	Testing schedule Test administration manuals
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Grades 11 and 12 who are exiting with an Alabama Occupational Diploma; small percentage of students whose IEP Teams determine this to be the exit document the students will pursue].				
2. Monitor the inclusion of students with disabilities receiving special education services in the state assessment program.	6-30-02 (annually)	Special Education	Focused Review Reports and LEA Profile	
3. Educate local education agencies (LEAs) regarding the participation of all students in the Alabama Student Assessment Program.	7-31-02	Student Assessment and Special Education	Agendas from 2002 Spring System Test Coordinator's Workshop and Special Education Coordinator's Meeting and the Student Assessment Handbook, section "Special Services."  PowerPoint presentation from February 7, 2002, teleconference with Special Education Coordinators	

			Flyer announcing assessment sessions at the 2002 Special Education Summer Academy
4. Survey of LEAs to determine the need for tests in languages other than English (number of LEP students by grade by primary home language).	10-31-02	Student Assessment and Federal Programs	Copy of survey form Results of survey
5. Review and revise Alabama Student Assessment Program Policies and Procedures for Students of Special Populations, Bulletin 1998, No. 11 (Includes appropriate accommodations for special education students, 504 students, and LEP students).	5-31-03	Student Assessment	Revised document
6. Monitor the inclusion of LEP students in the state assessment program.	6-30-03 (annually)	Federal Programs	Forms to be developed
7. Educate LEAs on revised Alabama Student Assessment	7-31-03	Student Assessment	Training schedule

Program Policies and Procedures for Students of Special Populations, Bulletin 1998, No. 11.			Copy of training materials
Alignment (IASA Sec. 1111(b) (3) (B) :			
1. Request technical assistance from U.S. Department of Education regarding revision of content standards and the relationship to assessments.	Student Assessment	4-30-02	Letter requesting assistance
2. Contract with consultants regarding revision of content standards and development of academic achievement standards to include alignment in reading/language arts and mathematics.	Curriculum Development and Student Assessment	5-31-02	Copy of contracts
3. Analysis of alignment of the Alabama Direct Assessment of Writing: Grade Ten with the content standards and academic achievement standards identifying any weaknesses.	Student Assessment	11-30-02	Report of Content and Bias Review Committee Report of Independent Evaluator



Make needed adjustments to ensure alignment.				
4. Analysis of alignment of the customized CRT (augmented NRT) with content standards and academic achievement standards identifying any weaknesses. Make needed adjustments to ensure alignment.	8-31-03	Student Assessment	Report of Content and Bias Review Committees Report of Independent Evaluator	
5. Based on data of first administration, make necessary adjustments of academic achievement standards descriptors and exemplars in order to ensure alignment with content standards and the Alabama Direct Assessment of Writing: Grade Ten.	8-31-04	Student Assessment	Report of committee Copy of final academic achievement standards descriptors and exemplars	
6. Conduct standard setting for CRT (augmented NRT) assessments in order to establish cut scores for academic achievement levels using data from the first administration. Make any	7-31-04	Student Assessment	Report of committees Copy of final academic achievement standards descriptors and exemplars	

necessary adjustments of academic achievement standards descriptors and exemplars in order to ensure alignment with content standards and the CRT (augmented NRT).				
Technical Quality (IASA Sec. 1111(b)(3)(C) :				
1. Report technical data for the AAA and Alabama Direct Assessment of Writing: Grade Five and Alabama Direct Assessment of Writing: Grade Seven (ADAW:5&7).	8-31-02	Student Assessment	Technical reports	
2. Report technical data for NRT.	10-31-02	Student Assessment	Technical report	
3. Report technical data for the AOPA.	10-31-03	Student Assessment	Technical report	
4. Report technical data for the Alabama Direct Assessment of Writing: Grade Ten (ADAW:10).	10-31-03	Student Assessment	Technical report	
5. Report technical data for CRT (augmented NRT). *	12-31-04	Student Assessment	Technical report	

Reporting (IASA Sec. 1111(b)(3)(H):			
1. Develop reports that communicate to educators, parents, and stakeholders how the assessment relates to the content standards and the academic achievement standards for the <i>Alabama Direct Assessment of Writing: Grade Ten</i> .	4-30-04	Student Assessment	Copy of reports
2. Develop reports that communicate to educators, parents, and stakeholders how the assessment relates to the content standards and the academic achievement standards for the CRT (augmented NRT).	5-31-04	Student Assessment	Copy of reports
3. Develop and pilot new standards-based accountability system using state assessments that include all students.	8-31-04	Student Assessment and Information System Services	Accountability model State Board of Education resolution

4. Report accountability system incorporating academic achievement standards.	8-31-04 (annually)	Student Assessment, Information System Services, and Office of Communication	Press release, reports to LEAs, and post on website
Disaggregated Reporting (IASA Sec. 1111(b)(3)(I):			
1. Report achievement data for current assessments including disaggregation and participation rates by subgroups.	8-31-02	Student Assessment, Information System Services, and Office of Communication	Press release, reports to LEAs, and post on website
2. Report achievement data for new assessments including disaggregation and participation rates by subgroups.	8-31-04 (annually)	Student Assessment, Information System Services, and Office of Communication	Press release, reports to LEAs, and post on website
No Child Left Behind Act of 2001:			
1. Review, revise, and adopt Alabama's content standards in science. - Distributed for stakeholder review and	8-31-04	Curriculum Development	State Board of Education resolution Copy of revised content standards

comment.  - Completed and adopted by State Board of Education.	8-31-05		
2. Development of standards-based assessments in Grades 3, 5, and 7.  - Complete test blueprints.  - Draft and field test items.  - Pilot assessments.	11-30-03  4-30-04  4-30-05	Student Assessment	Test blueprint  Field test data  Pilot test administration manuals
3. Dissemination of disaggregated data (gender, major racial/ethnic groups, English proficiency status, migrant status, students with disabilities as compared to nondisabled students, and economically disadvantaged students as compared to students who are not economically disadvantaged) at school	8-31-02 as available  8-31-03 all subgroups (annually)	Student Assessment, Information System Services, and Office of Communication	Sample reports based on tests administered in 2001-02

and district levels for assessments currently in use.				
4. Distribution of an itemized score analysis to support instructional improvement.	8-31-03 (annually)	Student Assessment and Office of Communication	Sample report based on tests administered in 2001-02	
5. Implementation of the English language proficiency testing required under Title I and Title III.  - Issue RFP.  - Selection and approval of assessment.  - Educate LEAs on language proficiency assessment.  - Administer to all LEP students.  - Define annual measurable objectives for gains in English proficiency as required in Sec. 3122.	8-31-03 (annually)	Student Assessment and Federal Programs	<p>Copy of RFP</p> <p>Report of committee</p> <p>Training schedule</p> <p>Testing schedule</p> <p>Report of committee</p> <p>Copy of reports</p>	

- Report results as required by NCLB.			
6. Participate in the National Assessment of Educational Progress in 2003 and 2005 and, if selected, participate in the field test in off-years.	3-31-02	Student Assessment	Consolidated application
<p>7. Distribution of state report card as required under Section 1111 of Title I to include:</p> <ul style="list-style-type: none"> <li>- Disaggregation of student achievement results by performance levels.</li> <li>- Percent of students not tested (disaggregated).</li> <li>- Comparison of annual objectives and actual performance for each student group.</li> <li>- All other report</li> </ul>	<p>9-30-02</p> <p>8-31-03</p> <p>8-31-05</p>	Office of Communication	Copy of state report card



card requirements will be met as quickly as possible consistent with implementation of final assessments.				
<p>8. A. Continued identification of schools in need of improvement based on data from the current assessments for all students in the grades assessed, and to also include:</p> <ul style="list-style-type: none"> <li>- Report performance of subgroups (of statistically reliable size).</li> <li>- Report the application of the 95% participation rule.</li> <li>- High school graduation rates and the other indicators required by NCLB.</li> </ul> <p>B. Establish AYP baseline, based on data from new assessments for all students in the grades</p>	<p>Student Assessment, Information System Services, and Office of Communication</p>	<p>9-30-02 as available</p> <p>8-31-03</p> <p>8-31-03</p> <p>8-31-04</p> <p>8-31-05</p>	<p>Description of school accountability system, to include the data source (assessments) and formula or decision sequence used to determine school classifications</p> <p>List of schools and districts identified for improvement</p> <p>Communication of baseline values and AYP design to schools and districts</p> <p>List of schools and districts identified for improvement</p>	

assessed.  - Use transitional rules under NCLB, Sec. 1116 to identify schools and districts in need of improvement.			
<p>9. Annual report to the Secretary as described in Sec. 1111(h) (4).</p> <ul style="list-style-type: none"> <li>- Information on state progress in developing all required state assessments.</li> <li>- Student achievement data disaggregated.</li> <li>- Data on acquisition of English proficiency by LEP.</li> <li>- Number and names of schools identified for school improvement, the reason for identification, and measures taken to address achievement problems.</li> </ul>	<p>8-31-02 (annually)</p> <p>8-31-03</p> <p>8-31-03</p> <p>8-31-03</p> <p>8-31-03</p> <p>8-31-03</p> <p>8-31-03</p>	Federal Programs	Annual report to the Secretary

- Number of students and schools that participated in public school choice and supplemental services.  - Information on quality of teachers and percent of classes taught by highly qualified teachers.			
10. All other requirements of NCLB pertaining to schools identified for improvement, corrective action, or restructuring during the period of the compliance agreement.	8-31-03	Federal Programs	Implementation and documentation of choice, supplemental services, corrective actions, as appropriate

\* Note: No final decision has been made to augment a NRT in Grades 3, 5, and 7.

Instead, a CRT may be developed and no NRT will be administered. This decision will be made after a review of the NRT that is selected in September 2002 and after input from the Test Advisory

**DEPARTMENT OF EDUCATION****Idaho State Department of Education;  
Written Findings and Compliance  
Agreement**

**AGENCY:** Office of Elementary and Secondary Education, Department of Education.

**ACTION:** Notice of written findings and compliance agreement.

**SUMMARY:** Section 457 of the General Education Provisions Act (GEPA) authorizes the U.S. Department of Education to enter into a compliance agreement with a recipient that is failing to comply substantially with Federal program requirements. In order to enter into a compliance agreement, the Department must determine, in written findings, that the recipient cannot comply until a future date with the applicable program requirements and that a compliance agreement is a viable means of bringing about such compliance. On March 29, 2002, the Assistant Secretary for Elementary and Secondary Education Dr. Susan B. Neuman entered into a compliance agreement with the Idaho State Department of Education (ISDE). Under section 457(b)(2) of GEPA, the written findings and compliance agreement must be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Dr. Zollie Stevenson, Jr., U.S. Department of Education, Office of Elementary and Secondary Education, 400 Maryland Avenue, SW., room 3W200, Washington, DC 20202. Telephone: (202) 260-1824.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotope, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

**SUPPLEMENTARY INFORMATION:** Under Title I, Part A of the Elementary and Secondary Education Act of 1965 (Title I), each State, including the District of Columbia and Puerto Rico, was required to develop or adopt, by the 1997-98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do. Each State also was required to develop or adopt performance standards, aligned with its

content standards, which describe three levels of proficiency to determine how well students are mastering the content standards. Finally, by the 2000-2001 school year, each State was required to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools in enabling students to meet the State's performance standards.

ISDE submitted, and the Department approved, evidence that it has content standards in at least reading/language arts and mathematics. In October 2000, ISDE submitted evidence of its final assessment system. The Department submitted that evidence to a panel of three assessment experts for peer review. Following that review, the Acting Deputy Assistant Secretary for Elementary and Secondary Education Tom Corwin concluded that ISDE's proposed final assessment system did not meet a number of the Title I requirements.

Section 454 of GEPA, 20 U.S.C. 1234c, sets out the remedies available to the Department when it determines that a recipient "is failing to comply substantially with any requirement of law" applicable to Federal program funds the Department administers. Specifically, the Department is authorized to—

- (1) Withhold funds;
- (2) Obtain compliance through a cease and desist order;
- (3) Enter into a compliance agreement with the recipient; or
- (4) Take any other action authorized by law.

20 U.S.C. 1234c(a)(1) through (a)(4).

In a letter dated October 16, 2001 to Dr. Marilyn L. Howard, State Superintendent of Public Instruction for Idaho, the Assistant Secretary Dr. Susan B. Neuman notified the ISDE that, in order to remain eligible to receive Title I funds, it must enter into a compliance agreement with the Department. The purpose of a compliance agreement is "to bring the recipient into full compliance with the applicable requirements of law as soon as feasible and not to excuse or remedy past violations of such requirements." 20 U.S.C. 1234f(a). In order to enter into a compliance agreement with a recipient, the Department must determine, in written findings, that the recipient cannot comply until a future date with the applicable program requirements, and that a compliance agreement is a viable means for bringing about such compliance.

On March 29, 2002, the Assistant Secretary issued written findings, holding that compliance by ISDE with the Title I standards and assessment requirements is genuinely not feasible until a future date. Having submitted its assessment system for peer review in October 2000, ISDE was not able to make the significant changes to its system that the Department's review required in time to meet the spring 2001 statutory deadline to have approved assessments in place. As a result, ISDE administered its unapproved assessment system in 2001. The Assistant Secretary also determined that a compliance agreement represents a viable means of bringing about compliance because of the steps the ISDE has already taken to comply, its commitment of resources, and the plan it has developed for further action. The agreement sets out the action plan that ISDE must meet to come into compliance with the Title I requirements. This plan, coupled with specific reporting requirements, will allow the Assistant Secretary to monitor closely the ISDE's progress in meeting the terms of the compliance agreement. The Idaho State Superintendent of Public Instruction, Dr. Marilyn L. Howard, signed the agreement on March 22, 2002 and the Assistant Secretary signed it on March 29, 2002.

As required by section 457(b)(2) of GEPA, 20 U.S.C. 1234f(b)(2), the text of the Assistant Secretary's written findings is set forth as appendix A and the compliance agreement is set forth as appendix B of this notice.

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(Authority: 20 U.S.C. 1234c, 1234f, 6311)

Dated: February 13, 2003.

Eugene W. Hickok,

*Under Secretary of Education.*

## Appendix A—Text of the Written Findings of the Assistant Secretary for Elementary and Secondary Education

### I. Introduction

The Assistant Secretary for Elementary and Secondary Education (Assistant Secretary) of the U.S. Department of Education (Department) has determined, pursuant to 20 U.S.C. 1234c and 1234f, that the Idaho State Department of Education (ISDE) has failed to comply substantially with certain requirements of Title I, Part A of the Elementary and Secondary Education Act of 1965 (Title I), 20 U.S.C. 6301 *et seq.*, and that it is not feasible for the ISDE to achieve full compliance immediately. Specifically, the Assistant Secretary has determined that ISDE failed to meet a number of the Title I requirements concerning the development of performance standards and an aligned assessment system within the statutory timeframe.

For the following reasons, the Assistant Secretary has concluded that it would be appropriate to enter into a compliance agreement with the ISDE to bring it into full compliance as soon as feasible. During the effective period of the compliance agreement, which ends three years from the date of these findings, the ISDE will be eligible to receive Title I funds as long as it complies with the terms and conditions of the agreement as well as the provisions of Title I, Part A and other applicable Federal statutory and regulatory requirements.

### II. Relevant Statutory and Regulatory Provisions

#### A. Title I, Part A of the Elementary and Secondary Education Act of 1965

Title I, Part A of the Elementary and Secondary Education Act of 1965 (Title I), 20 U.S.C. 6301 *et seq.*, provides financial assistance, through State educational agencies, to local educational agencies to provide services in high-poverty schools to students who are failing or at risk of failing to meet the State's student performance standards. Under Title I, each State, including the District of Columbia and Puerto Rico, was required to develop or adopt, by the 1997–98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do and performance standards, aligned with those content standards, that describe three levels of proficiency to determine

how well students are mastering the content standards.

By the 2000–2001 school year, Title I required each State to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools and school districts in enabling students to meet the State's performance standards. These assessments must meet the following requirements:

- The assessments must be aligned to a State's content and performance standards.
- They must be administered annually to students in at least one grade in each of three grade ranges: Grades 3 through 5, grades 6 through 9, and grades 10 through 12.
- They must be valid and reliable for the purpose for which they are used and of high technical quality.
- They must involve multiple measures, including measures that assess higher-order thinking skills.
- They must provide for the inclusion of all students in the grades assessed, including students with disabilities and limited English proficient students.
- They must provide individual reports.
- Results from the assessments must be disaggregated and reported by major racial and ethnic groups and other categories.

20 U.S.C. 6311(b)(3).<sup>1</sup>

#### B. The General Education Provisions Act

The General Education Provisions Act (GEPA) provides a number of options when the Assistant Secretary determines a recipient of Department funds is “failing to comply substantially with any requirement of law applicable to such funds.” 20 U.S.C. 1234c. In such case, the Assistant Secretary is authorized to—

- (1) Withhold funds;

(2) Obtain compliance through a cease and desist order;

(3) Enter into a compliance agreement with the recipient; or

(4) Take any other action authorized by law. 20 U.S.C. 1234c(a)(1) through (a)(4).

Under section 457 of GEPA, the Assistant Secretary may enter into a compliance agreement with a recipient that is failing to comply substantially with specific program requirements. 20 U.S.C. 1234f. The purpose of a compliance agreement is “to bring the recipient into full compliance with the applicable requirements of the law as soon as feasible and not to excuse or remedy past violations of such requirements.” 20 U.S.C. 1234f(a). Before entering into a compliance agreement with a recipient, the Assistant Secretary must hold a hearing at which the recipient, affected students and parents or their representatives, and other interested parties are invited to participate. At that hearing, the recipient has the burden of persuading the Assistant Secretary that full compliance with the applicable requirements of law is not feasible until a future date and that a compliance agreement is a viable means for bringing about such compliance. 20 U.S.C. 1234f(b)(1). If, on the basis of all the available evidence, the Assistant Secretary determines that compliance until a future date is genuinely not feasible and that a compliance agreement is a viable means for bringing about such compliance, the Assistant Secretary must make written findings to that effect and publish those findings, together with the substance of any compliance agreement, in the **Federal Register**. 20 U.S.C. 1234f(b)(2).

A compliance agreement must set forth an expiration date, not later than three years from the date of these written findings, by which time the recipient must be in full compliance with all program requirements. 20 U.S.C. 1234f(c)(1). In addition, a compliance agreement must contain the terms and conditions with which the recipient must comply during the period that agreement is in effect. 20 U.S.C. 1234f(c)(2). If the recipient fails to comply with any of the terms and conditions of the compliance agreement, the Assistant Secretary may consider the agreement no longer in effect and may take any of the compliance actions described previously. 20 U.S.C. 1234f(d).

<sup>1</sup> On January 8, 2002, title I of the Elementary and Secondary Education Act was reauthorized by the No Child Left Behind Act of 2001 (NCLB) (Pub. L. 107–110). The NCLB made several significant changes to the Title I standards and assessment requirements. First, it requires that each State develop academic content and student achievement standards in science by the 2005–06 school year. Second, by the 2005–06 school year, it requires a system of aligned assessments in each of grades 3 through 8 and once during grades 10 through 12. Third, it requires science assessments in at least three grade spans by the 2007–08 school year. Fourth, the NCLB significantly changes the definition of adequate yearly progress each State must establish to hold schools and school districts accountable, based on data from the 2001–02 test administration. Finally, by the 2002–03 school year, the NCLB requires State and school district report cards that include, among other things, assessment results disaggregated by various subgroups, two-year trend data, and percent of students tested.

### III. Analysis

#### *A. Overview of Issues To Be Resolved in Determining Whether a Compliance Agreement Is Appropriate*

In deciding whether a compliance agreement between the Assistant Secretary and the ISDE is appropriate, the Assistant Secretary must first determine whether compliance by the ISDE with the Title I standards and assessment requirements is genuinely not feasible until a future date. 20 U.S.C. 1234f(b). The second issue that the Assistant Secretary must resolve is whether the ISDE will be able, within a period of up to three years, to come into compliance with the Title I requirements. Not only must the ISDE come into full compliance by the end of the effective period of the compliance agreement, it must also make steady and measurable progress toward that objective while the compliance agreement is in effect. If such an outcome is not possible, then a compliance agreement between the Assistant Secretary and the ISDE would not be appropriate.

#### *B. The ISDE Has Failed To Comply Substantially With Title I Standards and Assessment Requirements*

In October 2000, the ISDE submitted evidence of its final assessment system. The Assistant Secretary submitted that evidence to a panel of three assessment experts for peer review. Following that review, the Acting Deputy Assistant Secretary for Elementary and Secondary Education Thomas Corwin concluded that ISDE's proposed final assessment system did not meet a number of the Title I requirements. Specifically, the Acting Deputy Assistant Secretary determined that the ISDE must do the following:

- Provide information on Idaho's proposed standards based assessment system.
- Provide evidence that its accountability system will allow the results of the Idaho final assessment system, including local assessments where applicable, to be the primary indicators of adequate yearly progress.
- Provide evidence that performance standards have been developed and implemented and that they are aligned with Idaho's content standards and the Idaho assessment system that is being developed.
- Provide clear and concise information on the enrollment of limited English proficient students and students with disabilities in the State at the assessed grade levels and provide information on the number of limited English proficient students and students

with disabilities who take the standard form of the Idaho assessments and the Idaho assessments with accommodations, and the number of those students exempted or excluded from the Idaho assessment program.

- Provide a copy of its inclusion policy for limited English proficient students and provide documentation that the State Board of Education has approved it. Included in that policy should be information on accommodations for limited English proficient students. A plan for implementing the new inclusion policies and for monitoring LEA compliance with the new inclusion policies when they are approved should also be provided.

- Submit information on the technical quality of the Idaho alternate assessment for students with disabilities as well as information that indicates the extent to which accommodations associated with the norm-referenced tests and State-developed assessments yield valid results for students with disabilities, as well as information regarding any accommodations that are planned for the Direct Mathematics and Writing assessments and the technical quality of those accommodated assessments.

- Document how it will incorporate performance data for all Idaho students into its reporting of results for assessment and accountability purposes.

- Provide evidence regarding the extent to which the components of the Idaho Assessment Program are aligned with Idaho standards.

- Provide technical information on each of the components of the Idaho Assessment Program and information on how Idaho ensures the fairness of its assessments for all students.

- Provide evidence on how the multiple measures that have been incorporated in the Idaho Assessment Program affect the validity, reliability, and fairness of those assessments.

- Disaggregate student performance by gender, race/ethnicity, migrant status, disability (versus non-disability), economic disadvantage (versus non-disadvantaged), and limited English proficiency status at the LEA and school levels. In addition, Idaho must add economic disadvantage to the categories that are currently being disaggregated at the State level.

- Define for LEAs which students are to be included in determining adequate yearly progress (AYP) for schools and LEAs.

- Provide a plan for evaluating the AYP of its small schools and K-3 schools.

#### *C. The ISDE Cannot Correct Immediately Its Noncompliance With the Title I Standards and Assessment Requirements*

Under the Title I statute, ISDE was required to implement its final assessment system no later than the 2000-2001 school year. 20 U.S.C. 6311(b)(6). ISDE submitted evidence of its assessment system in October 2000, but the Acting Deputy Assistant Secretary determined, on the basis of that evidence, that ISDE's system did not fully meet the Title I requirements. Due to the enormity and complexity of developing a new assessment system that addressed the Acting Deputy Assistant Secretary's concerns, the ISDE was not able to complete that task between the time it submitted its system for review and the Idaho 2001 assessment window. Thus, in 2001, the ISDE administered assessments that the Acting Deputy Assistant Secretary had determined did not meet the Title I requirements. As a result, the Assistant Secretary finds that it is not genuinely feasible for ISDE to come into compliance until a future date.

#### *D. The ISDE Can Meet the Terms and Conditions of a Compliance Agreement and Come Into Full Compliance With the Requirements of Title I Within Three Years*

At the public hearing, the ISDE presented evidence of its commitment and capability to come into compliance with the Title I standards and assessment requirements within three years. For example, Idaho entered into a contract to develop reading and mathematics assessments within one year at grades 4, 8 and 10. Idaho has established a process for developing performance descriptors and to define performance levels for its assessment system with broad based involvement of Idaho citizens and has established a timeline for approving the performance descriptors and performance levels. Idaho has also received approval from the Department for its academic content standards.

Finally, the ISDE has developed a comprehensive action plan, incorporated into the compliance agreement, that sets out a very specific schedule that the ISDE has agreed to meet during the next three years for attaining compliance with the Title I standards and assessment requirements. As a result, the ISDE is committed not only to coming into full compliance within three years, but to meeting a stringent, but reasonable, schedule for doing so. The action plan also demonstrates that the ISDE will be well

on its way to meeting the new standards and assessment requirements of the No Child Left Behind Act of 2001. The compliance agreement also sets out documentation and reporting procedures that the ISDE must follow. These provisions will allow the Assistant Secretary to ascertain promptly whether the ISDE is meeting each of its commitments under the compliance agreement and is on schedule to achieve full compliance within the effective period of the agreement.

The task of developing an assessment system that meets the Title I requirements is not a quick or easy one. However, the Assistant Secretary has determined that, given the commitment of the ISDE to comply with the terms and conditions of the compliance agreement, it is possible for the ISDE to come into full compliance with the Title I standards and assessment requirements within three years.

#### IV. Conclusion

For the foregoing reasons, the Assistant Secretary finds the following: (1) That full compliance by the ISDE with the standards and assessment requirements of Title I is not feasible until a future date; and (2) that the ISDE can meet the terms and conditions of the attached compliance agreement and come into full compliance with the Title I standards and assessment requirements within three years of the date of these findings. Therefore, the Assistant Secretary has determined that it is appropriate to enter into a compliance agreement with the ISDE. Under the terms of 20 U.S.C. 1234f, that compliance agreement becomes effective on the date of these findings.

Dated: March 29, 2002.

**Susan B. Neuman,**

*Assistant Secretary for Elementary and Secondary Education.*

#### **Compliance Agreement Under Title I of the Elementary and Secondary Education Act Between the United States Department of Education and the Idaho State Department of Education**

##### **Introduction**

Title I of the Elementary and Secondary Education Act of 1965 (Title I) required each State, along with the District of Columbia and Puerto Rico, to develop or adopt, by the 1997–98 school year, challenging content standards in at least reading/language arts and mathematics that describe what the State expects all students to know and be able to do. Title I also required each State to develop or adopt performance standards, aligned with its content

standards, that describe three levels of proficiency to determine how well students are mastering the content standards. Finally, by the 2000–2001 school year, Title I required each State to develop or adopt a set of student assessments in at least reading/language arts and mathematics that would be used to determine the yearly performance of schools in enabling students to meet the State's performance standards.

The Idaho State Department of Education (SDE) was not able to meet these requirements by the statutory deadlines. In order to be eligible to continue to receive Title I funds while working to comply with the statutory requirements, Dr. Marilyn Howard, Idaho's Superintendent of Public Instruction, indicated the Idaho SDE's interest in entering into a compliance agreement with the Office of Elementary and Secondary Education (OESE) of the United States Department of Education. On December 13, 2001, OESE conducted a public hearing regarding Idaho SDE's ability to come into compliance with the Title I standards and assessment requirements within three years. Based on testimony at that hearing, the Assistant Secretary for Elementary and Secondary Education (Assistant Secretary) determined that compliance by Idaho SDE with the Title I standards and assessment requirements was genuinely not feasible until a future date because of the "magnitude and complexity of meeting those requirements." The Assistant Secretary also determined that a compliance agreement represents a viable means of bringing about compliance because of the steps Idaho SDE has already taken to address its noncompliance, its commitment of resources, and the plans it has developed for further action. These plans are summarized in the Commitments and Timetable below.

Pursuant to this Compliance Agreement under 20 U.S.C. sec. 1234f, Idaho SDE must be in full compliance with the requirements of Title I no later than three years from the date of the Assistant Secretary's written findings, a copy of which is attached to, and incorporated by reference into, this Agreement. Specifically, Idaho SDE must ensure and document that it will have met the following requirements:

1. Provide information on Idaho's proposed standards based assessment system. Provide a copy of the development contract for the new assessment system.
2. Provide evidence that performance standards have been developed and implemented and that they are aligned with Idaho's content standards.

3. Provide a copy of the Limited English Proficient student (LEP) inclusion policy and documentation of State approval. Include in the LEP policy information on accommodations for LEP students. Provide a plan for implementing the new LEP inclusion policies and for monitoring LEA compliance with the new inclusion policies when they are approved. Provide clear and concise information on the enrollment of LEP students and students with disabilities (SWD) in the state at the assessed grade levels and provide information on the number of LEP students and SWDs who take the standard form of the Idaho assessments and the Idaho assessments with accommodations, and the number of those students excluded from the Idaho assessment program.

4. Provide evidence that the components of the Idaho Assessment Program are aligned with Idaho standards. Provide evidence that Idaho assessments are cognitively complex. Identify gaps and weaknesses of the assessment system. Provide evidence on how the multiple measures incorporated in the Idaho Assessment Program affect the validity, reliability, and fairness of those assessments.

5. Provide technical information on each of the components of the Idaho Assessment Program. Provide information on how Idaho will ensure the fairness of its assessments for all students. Submit information on the technical quality of the Idaho alternate assessment for SWD as well as information that indicates the extent to which accommodations yield valid results for SWD.

6. Provide evidence that student performance will be disaggregated by gender, race/ethnicity, migrant status, disability (versus non-disability), economic disadvantage (versus non-disadvantaged), and limited English proficiency status at the school, district, and state levels.

7. Demonstrate that the Idaho SDE has developed or adopted a set of high-quality, yearly student assessments that will be used as the primary means of determining the yearly performance of each local educational agency and school served under Title I, Part A. Provide evidence that the accountability system will allow the results of the Idaho final assessment system to be the primary indicators of adequate yearly progress. Document the incorporation of performance data for SWD and LEP students into the reporting of results for assessment and accountability purposes.

8. Provide a plan for evaluating the adequate yearly progress of small schools and K–2 schools.

9. Describe plans to comply with the No Child Left Behind Act of 2001 assessment and accountability requirements.

During the period that this Compliance Agreement is in effect, Idaho SDE is eligible to receive Title I, Part A funds if it complies with the terms and conditions of this Agreement, as well as the provisions of Title I, Part A and other applicable federal statutory and regulatory requirements. Specifically, the Compliance Agreement sets forth below action steps Idaho SDE must meet to come into compliance with its Title I obligations.

**Compliance Agreement, April 2002**

*U.S. Dept. of Education/Idaho State Dept. of Education*

The action steps incorporated into this Compliance Agreement may be

amended by joint agreement of the parties, provided full compliance can still be accomplished by the expiration date of the Agreement.

In addition to all of the terms and conditions set forth above, Idaho agrees that its continued eligibility to receive Title I, Part A funds is predicated upon compliance with statutory and regulatory requirements of that program that have not been addressed by this Agreement, including the requirements of the No Child Left Behind Act of 2001.

If the Idaho SDE fails to comply with any of the terms and conditions of this Compliance Agreement, including the action steps below, the U.S. Department of Education may consider the Agreement no longer in effect and may take any action authorized by law, including the withholding of funds or the issuance of a cease and desist order.

For Idaho's State Department of Education:  
Dated: March 22, 2002.

Dr. Marilyn Howard,  
*Superintendent.*

For the United States Department of Education:

Dated: March 22, 2002.

Susan B. Neuman,  
*Assistant Secretary, Office of Elementary and Secondary Education.*

*Date this Compliance Agreement becomes effective (Date of Assistant Secretary's Written Decision and Findings): March 21, 2002.*

*Expiration Date of this Agreement: March 29, 2005.*

**Compliance Agreement, April 2002**

*U.S. Dept. of Education/Idaho State Dept. of Education*

**BILLING CODE 4000-01-P**



**Idaho**  
**Title I Compliance Agreement**  
**Action Plan/Timeline**

**Goal 1: Provide information on Idaho's proposed standards based assessment system.**

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
1.1	Develop a Memorandum of Understanding to secure services for test development, administration, scoring and reporting.	MOU signed by Superintendent of Public Instruction and State Board of Education, Committee Member Lists	SDE, Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2002	State, Title I
1.2	Provide MOU to U.S. Department of Education.	MOU signed by Superintendent of Public Instruction and State Board of Education, Committee Member Lists	SDE, Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2002	State, Title I
1.3	Negotiate and sign a contract for services needed to develop an assessment system.	Release of contract	SDE, Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2002	State, Title II, Title VI, Special Education
1.4	Provide contract to U.S. Department of Education.	Signed contract	SDE, Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2002	State, Title I
1.5	Grades 4 and 8: Complete detailed design, testing blueprint and implementation activities required to create test items and test forms adequate to serve the purposes specified in the State's assessment ensuring validity, reliability and fairness.	Test Design Document; Validity and Reliability Studies, Bias Review	SDE, Test Coordinator, Bureau of Federal Programs, Title I	August 31, 2002	State, Title III, Title VI, Title II, Special Education
1.6	Develop procedures for test administration, scoring, data analysis, and reporting to meet high technical standards.	Copies of protocol and procedures manual	SDE, Test Coordinator, Bureau of Special Education, Title I	Oct. 31, 2002 & on going	Title VI, Special Education, State
1.7	Develop reports that are technically adequate for school and district accountability.	Copies of reports and accountability standards	SDE, Bureau of Technology, Test Coordinator, Bureau of Special Education, Title I, Bureau of Federal Programs	Oct. 31, 2002 & on going	Title VI, Special Education, State
1.8	Administer pilot tests for grades 4, 8	Letter NWREL and Report re: Alignment Study	SDE, Test Coordinator, Bureau of Federal Programs	December 31, 2002	Title VI, State
1.9	Procedures for test administration, scoring, data analysis, and reporting to meet high technical standards sent to U.S. Department of Education.	Copies of protocol and procedures manual	SDE, Test Coordinator, Bureau of Special Education, Title I	Oct. 31, 2002	Title VI, Special Education, State
1.10	Final review for completeness of items and review for bias for grades 4 and 8.	Report from NWREL and NWEA	SDE, Test Coordinator, Bureau of Federal Programs	January 31, 2003	Title III, Title VI, State
1.11	Complete test items and review for bias to ensure that results measured the standards for students of diverse backgrounds.	Blueprints of Pilot Tests	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	October 31, 2002	Title VI, State, Title II, Title III

I.12	Grades: 4 and 8 Administer Grade 4 and 8 tests	Schedule for administration Written confirmation that the test was administered	SDE, Test Coordinator	May 31, 2003	Title I
I.13	Demonstrate that there will be no gaps in the assessment plan.	Copy of assessment plan for grades 4, 8, and 10 (as compared to previous plan)  Reference State Board Rules on Thoroughness	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2003	Title II
I.14	Grade: 10 Complete detailed design, testing blueprint and implementation activities required to create test items and test forms adequate to serve the purposes specified in the State's assessment ensuring validity, reliability and fairness.	Test blueprint, Test design Document; Validity and Reliability Studies, Bias Review	State Board of Education	January 31, 2002	State Board of Education
I.15	Grade: 10 Complete test items and review for bias to ensure that results measured the standards for students of diverse backgrounds.	Test item specification document Reports of reviews	SDE, State Test Coordinator, Bureau of Federal Programs, Title I, State Board of Education	January 31, 2002	Title VI, State, Title II, Title III
I.16	Grade: 10 Administer field test of items to all 9 <sup>th</sup> graders and a representative sample of 10 <sup>th</sup> , 11 <sup>th</sup> , and 12 <sup>th</sup> graders.	Schedule for administration Written confirmation that the test was administered	SDE, Test Coordinator, Bureau of Federal Programs, Bureau of Curriculum and Accountability, Title I, State Board of Education	April 30, 2002	State Board of Education
I.17	Grade: 10 Technical review of field-tested items.	Technical report of tested items (from NWEA)	State Board of Education, SDE, Test Coordinator	July 31, 2002	State Board of Education
I.18	Grade: 10 Pilot test	Schedule of pilot test dates Written confirmation that the test was administered	State Board of Education, SDE, Test Coordinator	October 31, 2002	State Board of Education
I.19	Grade: 10 Conduct an external alignment study of test to state standards.	Alignment study	SDE, Test Coordinator, Bureau of Federal Programs	January 31, 2003	Title II

1.20	Grade: 10 Final review for completeness of items and review for bias for grade 10.	Report from NWREL and NWEA	SDE, Test Coordinator, Bureau of Federal Programs	March 31, 2003	Title III, Title VI, State
1.21	Grade: 10 Administer Grade 10 ISAT.	Schedule for administration Written confirmation that the test was administered	State Board of Education, SDE, Test Coordinator	May 31, 2003	State Board of Education
1.22	Grades: 3,7 Complete detailed design, testing blueprint and implementation activities required to create test items and test forms adequate to serve the purposes specified in the State's assessment ensuring validity, reliability and fairness.	Test Design Document; Validity and Reliability Studies, Bias Review	SDE, Test Coordinator, Bureau of Federal Programs, Title I	Aug. 31, 2003	State, Title III, Title VI, Title II, Special Education
1.23	Complete test items and review for bias to ensure that results measured the standards for students of diverse backgrounds.	Blueprints of Pilot Tests	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	October 31, 2003	Title VI, State, Title II, Title III
1.24	Administer pilot tests for grades 3 and 7.	Letter NWREL and Report re: Alignment Study	SDE, Test Coordinator, Bureau of Federal Programs	December 31, 2003	Title VI, State
1.25	Conduct an external alignment study of test to state standards.	Alignment study	SDE, Test Coordinator, Bureau of Federal Programs	Jan. 31, 2004	Title VI
1.26	Final review for completeness of items and review for bias for grades 3 and 7.	Report from NWREL and NWEA	SDE, Test Coordinator, Bureau of Federal Programs	January 31, 2004	Title III, Title VI, State
1.27	Grades: 3 and 7 Administer Grade 3 and 7 tests	Schedule for administration Written confirmation that the test was administered	SDE, Test Coordinator	May 31, 2004	Title I
1.28	Demonstrate that there will be no gaps in the assessment plan.	Copy of assessment plan for grades 3,4,7,8, and 10 (as compared to previous plan) Reference State Board Rules on Thoroughness	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2004	Title VI
1.29	Grades: 5,6 Complete detailed design, testing blueprint and implementation activities required to create test items and test forms adequate to serve the purposes specified in the State's assessment ensuring validity, reliability and fairness.	Test Design Document; Validity and Reliability Studies, Bias Review	SDE, Test Coordinator, Bureau of Federal Programs, Title I	Aug. 31, 2004	State, Title III, Title VI, Title II, Special Education
1.30	Complete test items and review for bias to ensure that results measured the standards for students of diverse backgrounds.	Blueprints of Pilot Tests	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	October 31, 2004	Title VI, State, Title II, Title III

1.31	Administer pilot tests for grades 5 and 6.	Letter NWREL and Report re: Alignment Study	SDE, Test Coordinator, Bureau of Federal Programs	December 31, 2004	Title VI, State
1.32	Conduct an external alignment study of test to state standards.	Alignment study	SDE, Test Coordinator, Bureau of Federal Programs	Jan. 31, 2005	Title II
1.33	Final review for completeness of items and review for bias for grades 5 and 6.	Report from NWREL and NWEA	SDE, Test Coordinator, Bureau of Federal Programs	January 31, 2005	Title III, Title VI, State
1.34	Grades: 5 and 6 Administer Grade 5 and 6 tests	Schedule for administration Written confirmation that the test was administered	SDE, Test Coordinator	May 31, 2005	Title I
1.35	Demonstrate that there will be no gaps in the assessment plan.	Copy of assessment plan for grades 3,4,5, 6, 7,8, and 10 Reference State Board Rules on Thoroughness	SDE, State Test Coordinator, Bureau of Federal Programs, Title I	April 30, 2005	Title VI
1.36	Administer tests.	Superintendent's letter with testing schedule	SDE, Test Coordinator	May 31, 2004	Title VI, Special Education, State

Goal 2: Provide evidence that performance standards have been developed and implemented and that they are aligned with Idaho's content standards and the Idaho assessment system that is being developed.

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
2.1	Establish a process for developing performance standards, including what processes will be involved in writing the descriptors e.g. performance descriptors, assessments in reading/language arts and math with at least two performance levels, aligned with content standards, challenging for all, broad based involvement, and performance standards the same for all students.	Written narrative outlining the process Descriptor development agenda Power Point presentations by consultants Descriptor development routine	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Federal Programs	August 31, 2002	Title I, State, Title II
2.2	Determine performance levels that describe at least two levels of high performance: such as Proficient and Advanced, to determine how well students are mastering the material in Idaho's Content Standards and a third performance level: such as Partially Proficient, to provide complete information of lower performing students towards achieving the proficient and advanced levels of performance.	Copy of Performance Levels Description of Process	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I, Bureau of Federal Programs, Bureau of Special Education	August 31, 2002	Title I, State, Title II
2.3	Document involvement of a broad base of education stakeholders in the development of performance descriptors ensuring diversity in the composition of the group, especially in the areas of expertise in special education and limited English proficient expertise.	Committee Members Outline of work plan Meeting agendas	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I, Bureau of Special Education, LEP	August 31, 2002	Title I, State, Title II
2.4	Document that the State has formally approved the draft performance descriptors.	Letter from State Superintendent of Public Instruction	Federal Bureau Chief	August 31, 2002	Title I, State
2.5	Develop grades 4, 8, and 10 performance descriptors to be sent to U.S. Department of Education.	Written descriptors Written description of the process used to develop Letter from State Superintendent of Public Instruction	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I	August 31, 2002	Title I, State, Title II
2.6	Review and finalize performance descriptors based on pilot assessment results.	Finalized written descriptors Agenda	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and	December 31, 2002	Title I, Title VI, Special Education State

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
		Committee Lists Test Blueprints, MOU, Copies of Reports	Accountability, Bureau of Special Education SDE, Test Coordinator	May 31, 2003	Title VI, State
2.7	Administer on grade level, state approved assessment for grades 4, 8, and 10, based on content standards and draft performance descriptors.				
2.8	Document involvement of a broad base of education stakeholders in the setting of cut scores ensuring diversity in the composition of the group, including expertise in the areas of special education and limited English proficiency.	Committee Lists Agenda	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2003	Title I, Title VI, Special Education State
2.9	Set cut scores on assessments by selecting a process and finalize procedures.	Description of the process for setting cut scores Cut Score Recommendations determined from technical information Formulas for Standard and Alternate Assessment Alternate Assessment Portfolio and Administrator's Manual	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2003	Title I, Title VI, Special Education State
2.10	Document that all students are included in the cut scores and that the cut scores are challenging for all students.	Summary of participation Testing Contractor NWREL Policy Governing Thoroughness and inclusion of all students	SDE, Test Coordinator Bureau of Federal Programs, NWEA	August 31, 2003	Title I, Title VI, Special Education State
2.11	Document that the State has formally approved the performance standards.	Letter from State Superintendent of Public Instruction	Federal Bureau Chief	August 31, 2003	Title I, State
2.12	Document that the cut scores are aligned with the performance standards and the content standards.	Final Alignment Study Report	SDE, Test Coordinator Bureau of Federal Programs	August 31, 2003	Title I, Title VI, Special Education State
2.13	Review and finalize performance standards based on assessment results that are aligned with the content standards for grades 4 and 8.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2003	Title I, Title VI, Special Education State

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
2.14	Send documentation to the U.S. Department of Education for formal peer review of performance cut scores.		SDE, Test Coordinator Bureau of Federal Programs	December 31, 2003	Title I, Title VI, Special Education State
2.15	Grades 3 and 7: Develop Grades 3 and 7 performance descriptors to be sent to U.S. Department of Education.	Written descriptors Written description of the process used to develop Letter from State Superintendent of Public Instruction	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I	August 31, 2003	Title I, State, Title II
2.16	Review and finalize grades 3 and 7 performance descriptors based on pilot assessment results.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2003	Title I, Title VI, Special Education State
2.17	Administer developed assessments based on content standards and draft performance descriptors.	Test Blueprints, MOU, Copies of Reports	SDE, Test Coordinator	May 31, 2004	Title VI, State
2.18	Document involvement of a broad base of education stakeholders in the setting of cut scores ensuring diversity in the composition of the group, including expertise in the areas of special education and limited English proficiency.	Committee Lists Agenda	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2004	Title I, Title VI, Special Education State
2.19	Set cut scores on assessments by selecting a process and finalize procedures.	Description of the process for setting cut scores Cut Score Recommendations determined from technical information Formulas for Standard and Alternate Assessment Alternate Assessment Portfolio and Administrator's Manual	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2004	Title I, Title VI, Special Education State
2.20	Document that all students are included in the cut scores and that the cut scores are challenging for all students.	Summary of participation Testing Contractor NWREL Policy Governing Thoroughness and inclusion of all students	SDE, Test Coordinator Bureau of Federal Programs, NWEA	August 31, 2004	Title I, Title VI, Special Education State

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
2.21	Document that the State has formally approved the performance standards.	Letter from State Superintendent of Public Instruction	Federal Bureau Chief	August 31, 2004	Title I, State
2.22	Document that the cut scores are aligned with the performance standards and the content standards.	Final Alignment Study Report	SDE, Test Coordinator Bureau of Federal Programs	August 31, 2004	Title I, Title VI, Special Education State
2.23	Review and finalize performance standards based on assessment results that are aligned with the content standards for grades 4 and 8.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2004	Title I, Title VI, Special Education State
2.24	Send documentation to the U.S. Department of Education for formal peer review of performance cut scores.		SDE, Test Coordinator Bureau of Federal Programs	December 31, 2004	Title I, Title VI, Special Education State
2.25	Grades 3 and 7: Develop Grades 3 and 7 performance descriptors to be sent to U.S. Department of Education.	Written descriptors Written description of the process used to develop Letter from State Superintendent of Public Instruction	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I	August 31, 2003	Title I, State, Title II
2.26	Review and finalize grades 3 and 7 performance descriptors based on pilot assessment results.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2003	Title I, Title VI, Special Education State
2.27	Administer developed assessments based on content standards and draft performance descriptors.	Test Blueprints, MOU, Copies of Reports	SDE, Test Coordinator	May 31, 2004	Title VI, State
2.28	Document involvement of a broad base of education stakeholders in the setting of cut scores ensuring diversity in the composition of the group, including expertise in the areas of special education and limited English proficiency.	Committee Lists Agenda	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2004	Title I, Title VI, Special Education State
2.29	Set cut scores on assessments by selecting a process and finalize procedures.	Description of the process for setting cut scores Cut Score Recommendations determined from technical information Formulas for Standard and Alternate Assessment	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2004	Title I, Title VI, Special Education State



	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
		Alternate Assessment Portfolio and Administrator's Manual			
2.30	Document that all students are included in the cut scores and that the cut scores are challenging for all students.	Summary of participation Testing Contractor NWREL Policy Governing Thoroughness and inclusion of all students	SDE, Test Coordinator Bureau of Federal Programs, NWEA	August 31, 2004	Title I, Title VI, Special Education State
2.31	Document that the State has formally approved the performance standards.	Letter from State Superintendent of Public Instruction	Federal Bureau Chief	August 31, 2004	Title I, State
2.32	Document that the cut scores are aligned with the performance standards and the content standards.	Final Alignment Study Report	SDE, Test Coordinator Bureau of Federal Programs	August 31, 2004	Title I, Title VI, Special Education State
2.33	Review and finalize performance standards based on assessment results that are aligned with the content standards for grades 4 and 8.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2004	Title I, Title VI, Special Education State
2.34	Send documentation to the U.S. Department of Education for formal peer review of performance cut scores.		SDE, Test Coordinator Bureau of Federal Programs	December 31, 2004	Title I, Title VI, Special Education State
2.35	Grades 5 and 6: Develop Grades 5 and 6 performance descriptors to be sent to U.S. Department of Education.	Written descriptors Written description of the process used to develop Letter from State Superintendent of Public Instruction	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I	August 31, 2004	Title I, State, Title II
2.36	Review and finalize grades 5 and 6 performance descriptors based on pilot assessment results.	Finalized written descriptors Agenda Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2004	Title I, Title VI, Special Education State
2.37	Administer developed assessments based on content standards and draft performance descriptors.	Test Blueprints, MOU, Copies of Reports	SDE, Test Coordinator	May 31, 2005	Title VI, State
2.38	Document involvement of a broad base of education stakeholders in the setting of cut scores ensuring diversity in the composition of the group, including expertise in the areas of special education and limited English proficiency.	Committee Lists Agenda	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2005	Title I, Title VI, Special Education State

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
2.39	Set cut scores on assessments by selecting a process and finalize procedures.	Description of the process for setting cut scores  Cut Score Recommendations determined from technical information  Formulas for Standard and Alternate Assessment  Alternate Assessment Portfolio and Administrator's Manual	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2005	Title I, Title VI, Special Education State
2.40	Document that all students are included in the cut scores and that the cut scores are challenging for all students.	Summary of participation  Testing Contractor NWREL  Policy Governing Thoroughness and inclusion of all students	SDE, Test Coordinator Bureau of Federal Programs, NWEA	August 31, 2005	Title I, Title VI, Special Education State
2.41	Document that the State has formally approved the performance standards.	Letter from State Superintendent of Public Instruction	Federal Bureau Chief	August 31, 2005	Title I, State
2.42	Document that the cut scores are aligned with the performance standards and the content standards.	Final Alignment Study Report	SDE, Test Coordinator Bureau of Federal Programs	August 31, 2005	Title I, Title VI, Special Education State
2.43	Review and finalize performance standards based on assessment results that are aligned with the content standards for grades 4 and 8.	Finalized written descriptors  Agenda  Committee Lists	SDE, Bureau of Federal Programs, Test Coordinator, Bureau of Curriculum and Accountability, Bureau of Special Education	December 31, 2005	Title I, Title VI, Special Education State
2.44	Send documentation to the U.S. Department of Education for formal peer review of performance cut scores.		SDE, Test Coordinator Bureau of Federal Programs	December 31, 2005	Title I, Title VI, Special Education State

Goal 3: Provide a copy of the LEP and SWD inclusion policy and provide documentation showing

it has been approved by the State Board of Education. Idaho will provide clear and concise information on the enrollment of LEP students and SWD in the State at the assessed grade levels and the number of those students who take the standard form of the Idaho assessment, the Idaho Assessment with accommodations, and the number of students excluded from the Idaho assessment program.

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
3.1	<b>Develop consistent coding assignments on student protocols for statewide assessments.</b>	Coding assignments will be implemented for all state assessments.	Bureau of Special Education, Bureau of Curriculum & Accountability	June 30, 2002	Special Education, State
3.2	Modify LEP and SWD policy that includes information on accommodations for LEP and SWD students.	Copy of Policy and Rules governing Thoroughness: 111- Assessments in Public Schools; 04- Testing Populations	SDE, Title I, LEP, Bureau of Special Education, SBOE	August 31, 2002	Title III, Title I,
3.3	Provide clear and concise information on the enrollment of LEP and SWD students in the State at the assessed grade levels	Copies of Disaggregated Test Reports School Profiles Annual LEP Child Count December 1 Annual Child Count information (Child count procedure are included) and performance Report Annual Legislative Report Special study commissioned by legislature (HCR 54) Test Guidelines and Manual	SDE, LEP, Bureau of Special Education, State Test Coordinator, Title I	August 31, 2002	State, Title III, Title VI, Special Education
3.4	Investigate the accommodations and/or adaptations for LEP and SWD taking the tests under development with NWEA.		SDE, Test Coordinator, LEP, Bureau of Special Education	December 31, 2002	State, Title III, Title II, Special Education

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
3.5	Develop a plan to modify, based on new assessments, Idaho's inclusion policy, to include accommodations or adaptations for LEP students and SWD.	Copy of new guidelines and policy Superintendent of Public Instructions approval letter	SDE, Test Coordinator, LEP, Bureau of Special Education	January 31, 2003	State, Title III, Special Education Title II
3.6	Develop a plan for implementing the LEP and SWD inclusion policies and for monitoring LEA compliance with the inclusion policies.	Dissemination of plan to LEAs and public Agenda on community meetings	SDE, Test Coordinator, LEP, Bureau of Special Education	January 31, 2003	State, Title III, Special Education
3.7	All LEP and SWD will be required to take state assessments (with or without accommodations/adaptations) and the results will be included in the state's accountability reports.	State's Accountability Reports	SDE, Test Coordinator, LEP, Bureau of Special Education, Contractor NWEA	May 31, 2003	State, Title III, Special Education Title II
3.8	Provide information on the number of LEP and SWD students who take the standard form of the Idaho assessments.	Copy of Disaggregated Testing data	SDE, Test Coordinator, LEP, Bureau of Special Education, Contractor NWEA	July 31, 2003	State, Special Education
3.9	<b>Provide complete participation data for students with disabilities and LEP students so that the State's inclusion policies relating to assessment, reporting, and accountability can be evaluated and submit to U.S. Department of Education</b>	Participation Report	Office of Technology and Information Services  SDE, Test Coordinator, LEP, Bureau of Special Education, Contractor NWEA	August 31, 2003	State, Special Education
3.10	Provide the number of LEP and SWD students excluded from the Idaho assessment program.	Annual Testing Reports and test manual	SDE, Test Coordinator, LEP, Bureau of Special Education, Contractor NWEA	August 31, 2003	State, Special Education
3.11	<b>Ensure consistent implementation of standards and assessment with regard to students with disabilities.</b>	Bureau of Special Education Implementation Manual, September 2002  Idaho Alternate Assessment Administration Manual, 2001  Training modules on IEP assessment decisions	Bureau of Special Education	April 30, 2002	Bureau of Special Education, State
3.12	<b>Document all districts in Idaho currently use the Idaho Alternate Assessment (IAA) for students who are not able to participate in the general statewide assessments.</b>	Participation data reported on state and district data reports.  Results from 2001-2002 IAA will be evaluated by an outside contractor	Bureau of Special Education	April 30, 2002	

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
3.13	Ensure broad based participation in the development and piloting of the IAA.	Final report from Dr. Stephen Elliott on the 2000-2001 evaluation of the Idaho Alternate Assessment	Bureau of Special Education	April 30, 2002	
3.14	Provide disaggregated assessment performance data on students with disabilities.	Annual district data reports Bureau of Special Education monitoring system Title 1 Annual Performance Report	Bureau of Special Education	August 31, 2003	Special Education

**Goal 4: Provide evidence that the components of the Idaho assessment program are aligned with Idaho standards. Provide evidence that Idaho assessments are cognitively complex. Identify gaps and weaknesses of the assessment system. Provide evidence on how the multiple measures incorporated in the Idaho assessment program affect the validity, reliability, and fairness of those assessments.**

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
4.1	Develop a process to ensure alignment of content standards for grades 4, 8, and 10, with the assessment. Consider validity, reliability and cognitive complexity.	Agreement with NWREL detailing services	SDE, Test Coordinator, Bureau of Federal Programs, Title I	August 31, 2002	Title I, Title VI, State Title II
4.2	Idaho will contract with experts to conduct studies with regard to new assessment system to assure that it is aligned with Idaho content and performance standards.	Test Contractor Report NWREL contract for alignment study Alternate Assessment alignment study by Dr. Stephen Elliott	SDE, Test Coordinator Title I, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2002	Title I Title II State Special Education
4.3	Document how performance descriptors are aligned with the content standards.	NWREL Alignment Report	SDE, Test Coordinator, Bureau of Curriculum and Accountability, Title I	August 31, 2003	Title I, State, Title II
4.4	Complete an analysis of the alignment of the assessment and standards identifying any gaps and weaknesses in the alignment.	NWREL Alignment Report	SDE, Test Coordinator, Bureau of Federal Programs, Title I	August 31, 2003	Title II, Title I, Title VI, State
4.5	Complete any needed adjustments in the test forms for grades 4, 8, 10.	NWREL Alignment Report NWEA technical report	SDE, Test Coordinator, Bureau of Federal Programs	December 31, 2003	Title VI, Special Education, State
4.6	Results of alignment study sent to U.S. Department of Education.	Alignment Study	SDE, Test Coordinator	March 31, 2004	Title VI, Special Education, State

**Goal 5: Provide technical information on each of the components of the Idaho Assessment Program. Provide information on how Idaho will ensure the fairness of its assessments for all students. Submit information on the technical quality of Idaho's alternate assessments for SWD as well as information that indicates the extent to which accommodations yield valid results for SWD.**

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
5.1	Establish external technical advisory team to review technical quality of the Idaho assessment system.	List of team members Vitals of team members Minutes from quarterly meetings	State Superintendent of Public Instruction, Test Coordinator,	April 31, 2002	Title II
5.2	Complete detailed design, testing blueprint and implementation activities required to create test items and test forms adequate to serve the purposes specified in the State's assessment ensuring validity, reliability and fairness for grades 4, 8, and 10.	Test Design Document; Validity and Reliability Studies, Bias Review	SDE, Test Coordinator, Bureau of Federal Programs, Title I	August 31, 2002	State, Title III, Title VI, Title II, Special Education
5.3	Provide evidence that Idaho assessments possess cognitive complexity.	Test Contractor Report NWREL Alignment Study Test Blueprints	SDE, Test Coordinator Title I, Bureau of Curriculum and Accountability	January 31, 2003	Title I Title II State
5.4	Identify gaps and weaknesses of the assessment system.	Test Contractor Report NWREL Alignment Study	SDE, Test Coordinator Title I, Bureau of Curriculum and Accountability	January 31, 2003	Title I Title II State
5.5	Provide evidence on how the multiple measures that have been incorporated in the Idaho Assessment Program affect the validity, reliability, equity, lack of bias, and fairness of those assessments.	Test Contractor Report NWREL Alignment Study	SDE, Test Coordinator Title I, Bureau of Curriculum and Accountability	January 31, 2003	Title I Title II State
5.6	Review of technical quality sent to U.S. Department of Education.	Technical Quality Reports	SDE, Test Coordinator	August 31, 2003	Title VI, Special Education, State
5.7	Develop technical manuals that contain such information as validity, reliability, fairness/accessibility, cognitive complexity, and comparability of results.	Technical Manuals	SDE, Test Coordinator, Bureau of Special Education, Title I	August 31, 2003	Title VI, Special Education, State

**Goal 6: Provide evidence that student performance will be disaggregated by gender, race/ethnicity, migrant status, disability (versus non-disability), economic disadvantage (versus non-disadvantaged), and limited English proficiency status at the school, district, and state level.**

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
6.1	Describe procedures for annually reporting results.	Annual School, District, and State Accountability Report Cards	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI
6.2	Provide a workplan and timeline for the development and dissemination of these performance profiles for every district and school.	Workplan and Timeline	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI
6.3	Document that all students are included in school profiles.	Annual School, District, and State Accountability Report Cards	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI
6.4	Develop template for Continuous School Improvement Profile and Processes.	Minutes of Workgroup Meetings	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI
6.5	Implement data collection system <ul style="list-style-type: none"> <li>Statewide training of teachers and stakeholders</li> <li>Redesign assessment answer sheets</li> <li>Establish a uniform code for information about the participation of sub-population groups</li> </ul>	Workplan and Timeline Agenda Minutes of Meetings Power Point Presentations	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI
6.6	Design a reporting template that has all reporting categories of disaggregated student achievement by student performance levels.	Reporting Template SDE Web Site	SDE Continuous School Improvement Team and Bureau of Technology	August 31, 2002	State, Title I, Title VI



Goal 7: Demonstrate that the State has developed or adopted a set of high-quality, yearly student assessments that will be used as the primary means of determining the yearly performance of each local educational agency and school served under Title I, Part A. Provide evidence that the accountability system will allow the results of the Idaho final assessment system to be the primary indicator of adequate yearly progress. Document the incorporation of performance data for SWD and LEP students into the reporting of results for assessment and accountability purposes.

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
7.1	Describe the plan to include only State level tests, as outlined in our assessment plan and compliance agreement to be used as the academic measures of progress in the accountability system will allow the results of the Idaho final assessment system, and to be the primary indicators of adequate yearly progress.	Copy of proposed state assessment plan for the next five years  State Board of Education Rules Governing Thoroughness  Memorandum of Understanding with NWEA	SDE, Test Coordinator, Title I, State Superintendent of Public Instruction	June 30, 2002	Title I, State, Title II
7.2	Idaho will develop a definition of adequate yearly progress that requires continuous improvement towards goal of having all students reaching proficiency.	AYP guide  2003 Consolidated State Plan	Test Coordinator, Title I, Federal Bureau Chief	August 31, 2002	Title I, State, Title II

Goal 8: Provide a plan for evaluating the AYP of its small schools and K-2 schools.

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
8.1	Research various strategies for evaluating AYP in small schools and K-2 schools.	Samples from other states	SDE, Title I, State, Test Coordinator, Bureau of Special Education	August 31, 2002	Title I, Title II
8.2	Design a plan that will include performance of multiple grades for evaluating AYP of small schools and K-2 schools incorporating assessment data from state assessments.	Copy of plan and description of process	SDE, Title I, State, Test Coordinator, Bureau of Special Education	June 30, 2002	Title I, Title II

Goal 9: Comply with the NCLB Act of 2001 assessment and accountability requirements.

	Component or Measurable Outcome	Documentation	Office Responsible	Date	Fiscal Resources
9.1	Compliance agreement will have until 6 months from the date of the agreement or 30 days after publication of final regulations (whichever comes first) to determine the specific tasks and dates required to satisfy each goal of NCLB.	Documented in Consolidated Application	Title I	Oct. 31, 2002	State and Title II
9.2	Technical assistance pending from US Department of Education.	Documented in Consolidated Application Letter requesting USDE assistance	US Dept of Ed	March 31, 2002 and ongoing	US Department of Education
9.3	Participation in the National Assessment of Educational Progress in 2003 and 2005 and, if selected, participation in the field test in off years.	Documented in Consolidated Application	Federal Programs and Test Coordinator	March 31, 2002 and ongoing	NAEP
9.4	Content standards in science: Distributed for stakeholder review and comment Completed and adopted by Board of Education	List of participants involved in developing and reviewing MCREL Summary Report Administrative Rules of State Board of Education Idaho Achievement Standards approved by Office of Elementary and Secondary Education, August 2001	Bureau of Curriculum and Accountability	April 8, 2001	State Resources

9.5	Develop standards-based assessments in remaining grades 3-8 Complete test blueprint Develop & field test items Pilot assessments in the grades not tested in 2004	Test blueprint Field test data Pilot administration manual Memorandum of Understanding with Contractor, SDE, and SBOE	LEP, Title I, Bureau of Special Education, Test Coordinator, Bureau of Curriculum and Accountability	Fall 2003 Spring 2004 Spring 2005	State and Title VI
9.6	Distribution of an itemized score analysis to support instructional improvement.	Sample report based on test administered in 2001-02	SDE, Test Coordinator, NWEA	August 31, 2003	State and Title VI
9.7	Implementation of the English language proficiency testing required under Title I and Title III Identify test that will be used Administer to all LEP students Define annual measurable objectives for gains in English proficiency as required in Sec. 3122 Report results as required by NCLB Language proficiency must be assessed two years after exiting program.	Instructions to schools, test administration manuals, sample reports  Memorandum of Understanding with Contractor	LEP, Title I, Bureau of Special Education, Test Coordinator	2002-03 and Annually thereafter	Title III, Title II, Title VI, and Special Education
9.8	Distribution of a state report card as required under Section 1111 of Title I. State report card must include the following assessment components by dates shown <ul style="list-style-type: none"> <li>Disaggregated student achievement results by performance level by August 31, 2002</li> <li>Percent of students not tested, disaggregated by August 31, 2002</li> <li>Comparison between annual objectives and actual performance for each student group by August 31, 2004</li> </ul> All other report card requirements must be met as quickly as possible, consistent with implementation of final assessments.	Copy of state report card	Test Coordinator, Bureau of Special Education, Title I	August 2002 and ongoing	State, Title VI, Special Education
9.9	Continued identification of schools in need of improvement, based on data from the current assessment(s) for all children in the grades assessed and, to also include:	Description of school accountability system, to include the data source (assessments) and formula or decision sequence used to	Test Coordinator, Bureau of Special Education, Title I	August 31, 2002 and ongoing	State, Title V, Special Education

	<ul style="list-style-type: none"> <li>• Performance of subgroups (of statistically reliable size)</li> <li>• Application of the 95% participation rule</li> <li>• HS graduation and the other indicators required by NCLB</li> </ul>	determine school classifications.  List of schools & districts identified for improvement			State, Title I, Special Education
9.10	<p>Establish AYP baseline, based on data from the new assessment(s) for all children in the grades assessed</p> <p>Use transitional rules under NCLB, Sec. 1116 to identify schools in need of improvement</p>	<p>Communication of baseline values and AYP design to schools and districts</p> <p>List of schools &amp; districts identified for improvement</p>	Title I, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2003	State, Title I, Special Education
9.11	<p>Annual report to the Secretary as described in Section 1111(h)(4)</p> <ul style="list-style-type: none"> <li>• Information on State progress in developing all required academic assessments (2002-03)</li> <li>• Student achievement data, disaggregated (2002-03)</li> <li>• Data on acquisition of English proficiency by LEP (2002-03)</li> <li>• Number and names of schools identified for school improvement, the reason for identification, and measures taken to address achievement problems</li> <li>• Number of students and schools that participated in public school choice and supplemental services</li> <li>• Information on quality of teachers and percent of classes taught by highly qualified (2002-03)</li> </ul>	Data will be reported as part of the Annual Title I Performance Report	Title I, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2002 and Annually thereafter	State, Title I, Special Education
9.12	All other requirements of NCLB pertaining to schools identified for improvement, corrective action, or restructuring during the period of the compliance agreement	Implementation and documentation of choice, supplemental services, corrective actions, as appropriate	Title I, Bureau of Curriculum and Accountability, Bureau of Special Education	August 31, 2002 and ongoing	State, Title I, Special Education

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****[Docket No. PR03-7-000]****AIM Pipeline, LLC; Notice of Petition for Rate Approval**

February 13, 2003.

Take notice that on February 3, 2003, AIM Pipeline, LLC (AIM) filed, pursuant to section 284.123(b)(2) of the Commission's Regulations, a petition for rate approval for transportation services rendered pursuant to Section 311(a)(2) of the Natural Gas Policy Act of 1978 (NGPA). AIM proposes a system-wide maximum interruptible transportation rate of \$0.2711 per MMBtu effective February 1, 2003.

AIM's petition states that it is an intrastate pipeline company within the meaning of section 2(16) of the NGPA, 15 U.S.C. 3301(16). AIM provides interruptible transportation service pursuant to section 311(a)(2) of the NGPA through its facilities located in Mississippi.

Pursuant to section 284.123(b)(2)(ii), if the Commission does not act within 150 days of the date of this filing, the rates will be deemed to be fair and equitable and not in excess of an amount which interstate pipelines would be permitted to charge for similar transportation service. The Commission may, prior to the expiration of the 150 day period, extend the time for action or institute a proceeding to afford parties an opportunity for written comments and for the oral presentation of views, data, and arguments.

Any person desiring to participate in this rate proceeding must file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed with the Secretary of the Commission on or before March 3, 2003. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This petition for rate approval is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits I the docket number field to access the document. For assistance, please contact FERC Online

Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contract (202) 502-8659. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

**Magalie R. Salas,**  
*Secretary.*

[FR Doc. 03-4122 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P****DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****[Docket No. CP01-5-003]****Algonquin Gas Transmission Company Notice of Amendment**

February 13, 2003.

Take notice that on February 5, 2003, Algonquin Gas Transmission Company (Algonquin), 5400 Westheimer Court, Houston, Texas 77056-5310, filed in Docket No. CP01-5-003, an application, pursuant to Section 7(c) of the Natural Gas Act and part 157 of the Federal Energy Regulatory Commission's regulations to amend the certificate of public convenience and necessity issued December 21, 2001, in Docket No. CP01-5-000, as amended June 4, 2002, in Docket No. CP01-5-002, for Algonquin's HubLine project, as more fully described in the application. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Specifically, Algonquin requests authorization to construct approximately 6.64 miles of 24-inch pipeline and 0.31 miles of 8-inch pipeline extending from the terminus of the originally certificated Deer Island Lateral portion of Algonquin's HubLine project across Boston Harbor through portions of East Boston, Chelsea, and Everett, Massachusetts to a connection with Algonquin's existing J-System. Algonquin also proposes to construct three meter stations and other related

facilities. Algonquin refers to the proposed new facilities as the Everett Extension project, while referring to the Everett Extension project and the Deer Island Lateral, collectively, as HubLine Phase II. The total cost of the HubLine Phase II facilities is estimated to be approximately \$110 million.

Algonquin also requests authorization to implement a revised initial incremental surcharge for service on the entire HubLine Phase II facilities in lieu of the previously approved rate for service solely on the Deer Island Lateral. Algonquin states that firm transportation service will be rendered to HubLine Phase II shippers pursuant to Algonquin's Rate Schedule AFT-1. Algonquin proposes no change to the previously approved surcharge for service on the HubLine mainline facilities.

Algonquin requests that the Commission issue a final certificate granting the authorizations requested on or before December 15, 2003, in order to place the HubLine Phase II facilities into service in a time frame consistent with that of the shippers who have requested service on such facilities. Relatedly, Algonquin has requested an extension of the originally authorized time to construct and place into service the Deer Island Lateral to coincide with that of the Everett Extension project, thereby enabling Algonquin to construct the HubLine Phase II facilities at one time.

Any questions regarding this application should be directed to Mr. Steven E. Tillman, General Manager, Regulatory affairs, Algonquin Gas Transmission Company, P.O. Box 1642, Houston, Texas 77251-1642, or call (713) 627-5113 or FAX (713) 627-5947.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the

Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process.

Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project.

This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Protests and interventions may be filed electronically via the internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

*Comment Date:* March 6, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4112 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP03-228-001]

#### Alliance Pipeline L.P.; Notice of Compliance Filing

February 13, 2003.

Take notice that on February 6, 2003., Alliance Pipeline L.P. (Alliance) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Substitute First Revised Sheet No. 253, proposed to become effective February 1, 2003.

On December 31, 2002, Alliance filed First Revised Sheet No. 253 to amend the General Terms and Conditions (GTC) of its FERC Gas Tariff to permit Alliance to terminate a temporary release of capacity, upon 30-days written notice to the replacement shipper, where (i) Alliance has terminated the releasing shipper's Firm Transportation Agreement or Master Capacity Release Agreement in accordance with GTC Section 8 (Default and Termination); and (ii) the rate stated in the replacement shipper's applicable Capacity Release Schedule is less than the rate that the releasing shipper was obligated to pay Alliance.

Alliance further proposed that a replacement shipper may avoid termination of the temporary release if, prior to the end of the 30-day notice period, the replacement shipper agrees that, beginning the first day after the end of the 30-day notice period, it will pay, for the remainder of the term of the release, either the rate the former releasing shipper was obligated to pay Alliance, the maximum applicable Recourse Reservation and Usage

Charges as stated in the tariff for the applicable service, or a rate mutually agreed upon by Alliance and the Shipper.

By order issued January 30, 2003, the Commission accepted Alliance's filing, to be effective February 1, 2003, subject to Alliance filing clarifying language specifying that the replacement shipper may retain the released capacity by agreeing to pay the "lesser of" the available rate options. By its filing, Alliance is proposing to add the required clarifying language. Alliance states further that, because the relative relationship between its recourse and negotiated rates will not necessarily remain static over the term of any particular release of capacity, it is also adding further clarifying language to provide the replacement shipper with the right to determine which of the available rate options will provide the lowest effective rate over the remaining term of a capacity release.

Alliance states that copies of its filing have been mailed to all customers, state commissions, and other interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. *Protest Date:* February 18, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4125 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP91-161-028]

**Columbia Gas Transmission Corporation; Notice of Refund Report**

February 13, 2003.

Take notice that on October 21, 2002, Columbia Gas Transmission Corporation (Columbia Gas) tendered for filing a report on the flow-back to customers of funds received from insurance carriers for environment costs attributable to Columbia Gas' Docket No. RP91-161 settlement period.

Columbia Gas states that it allocated such recoveries among customers based on their fixed cost responsibility for services on the Columbia Gas system during the period December 1, 1991 through January 31, 1996, the period of the Docket No. RP91-161 settlement.

Columbia Gas further states that it provided copies of the report to all customers who received a share of the environmental issuance recoveries and all state commissions whose jurisdiction includes the location of any such recipient.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Comment Date:* February 20, 2003.

**Magalie R. Salas,**  
*Secretary.*

[FR Doc. 03-4126 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP96-389-075]

**Columbia Gulf Transmission Company; Notice of Negotiated Rate Filing**

February 13, 2003.

Take notice that on February 7, 2003., Columbia Gulf Transmission Company (Columbia Gulf) tendered for filing, as part of its FERC Gas Tariff, Second Revised Volume No. 1, Third Revised Sheet No. 20C; Third Revised Sheet No. 20E; Third Revised Sheet No. 20F; and Third Revised Sheet No. 20G, with an effective date of February 1, 2003.

Columbia Gulf states that it is filing these tariff sheets to comply with the Commission's orders approving negotiated rate agreements in Docket Nos. RP96-389-052, 055, 060 and 067. The instant filing contains revised tariff sheets reflecting the rate effective on February 1, 2003.

Columbia Gulf states further that it has served copies of the filing on all

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Comment Date:* February 19, 2003.

**Magalie R. Salas,**  
*Secretary.*

[FR Doc. 03-4127 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP02-534-004]

**Guardian Pipeline Company, L.L.C.; Notice of Negotiated Rates**

February 13, 2003.

Take notice that on February 11, 2003., Guardian Pipeline Company, L.L.C. (Guardian) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Fourth Revised Sheet No. 6, proposed to be effective February 1, 2003.

Guardian states that the purpose of this filing is to reflect a change in the primary receipt points on a negotiated rate agreement that was amended to be effective February 1, 2003.

Guardian states that copies of this tariff filing are being served on all jurisdictional customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Comment Date:* February 24, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4124 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER03-293-000]

#### North Branch Resources, LLC; Notice of Issuance of Order

February 13, 2003.

North Branch Resources, LLC (North Branch) filed an application requesting authority to transact at market-based rates along with the accompanying tariff. The proposed market-based rate tariff provides for the sale of capacity and energy at market-based rates. North Branch also requested waiver of various Commission regulations. In particular, North Branch requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by North Branch.

On February 11, 2003., pursuant to delegated authority, the Director, Division of Tariffs and Market Development—South, granted the request for blanket approval under part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by North Branch should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is March 13, 2003.

Absent a request to be heard in opposition by the deadline above, North Branch is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of North Branch, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued

approval of North Branch's issuances of securities or assumptions of liability.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4115 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. GT02-38-004]

#### Northern Natural Gas Company; Notice of Compliance Filing

February 13, 2003.

Take notice that on February 10, 2003., Northern Natural Gas Company (Northern), tendered for filing in its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets, with an effective date of February 23, 2003:

Substitute Second Revised Sheet No. 284  
Substitute Third Revised Sheet No. 285  
Substitute Original Sheet No. 285A  
Original Sheet No. 285B  
Sixth Revised Sheet No. 289

Northern states that the filing is being made in compliance with the Commission's order issued on January 29, 2003, in Docket No. GT02-38, *et al.* (Order) regarding the creditworthiness and capacity release provisions of Northern's tariff.

Northern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the

appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Protest Date:* February 24, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4117 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER03-300-001]

#### Pacific Gas and Electric Company; Notice of Filing

February 13, 2003.

Take notice that on February 12, 2003, Pacific Gas and Electric Company (PG&E) filed an errata to replace and correct tariff sheets to its December 20, 2002 filing of Transmission Owner Tariff (TO Tariff) rate for the Transmission Revenue Balancing Account Adjustment, the Reliability Services rate, and the Transmission Access Charge Balancing Account Adjustment also set forth in its TO Tariff. The Errata corrects certain word processing errors in Appendices I and II of the filing. None of the replacement pages contains a change in rates as originally proposed in the December 20, 2002 filing.

PG&E states that copies of this filing have been served upon the California Independent System Operator (ISO), Scheduling Coordinators registered with the ISO, Southern California Edison Company, San Diego Gas & Electric Company, the California Public Utilities Commission and other parties to the official service lists in this docket and recent TO Tariff rate cases, FERC Docket Nos. ER00-2360-000 and ER01-66-000.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC



20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866)208-3676, or for TTY, contact (202)502-8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

*Comment Date:* February 24, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4116 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP99-518-035]

#### PG&E Gas Transmission, Northwest Corporation; Notice of Negotiated Rates

February 13, 2003.

Take notice that on February 11, 2003., PG&E Gas Transmission, Northwest Corporation (GTN) tendered for filing to be part of its FERC Gas Tariff, Second Revised Volume No. 1-A, Fourth Revised Sheet No. 15 and First Revised Sheet No. 18. GTN requests that the Commission accept the proposed tariff sheets to be effective February 11, 2003.

GTN states that these sheets are being filed to reflect the implementation of three negotiated rate agreements.

GTN further states that a copy of this filing has been served on GTN's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Comment Date:* February 24, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4128 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP01-243-002]

#### Pine Needle LNG Company, LLC; Notice of Compliance Filing

February 13, 2003.

Take notice that on February 7, 2003, Pine Needle LNG Company, LLC (Pine Needle), tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1,

2nd Sub Second Revised Sheet No. 89 and Substitute Original Sheet No. 89A, with an effective date of January 1, 2003.

Pine Needle states that the instant filing is submitted in compliance with the Commission's letter order issued January 24, 2003 (January 24 Order) in the referenced docket. The January 24 Order directed Pine Needle to refile, within 15 days of the order, tariff sheets to implement NAESB Standards 2.3.32, 4.3.23 and 4.3.54 to the extent these standards pertain to matters other than netting and trading and imbalances.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

*Protest Date:* February 19, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4123 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****Notice of Availability of Executive Summary and Index Templates**

February 13, 2003.

**San Diego Gas & Electric Company, Complainant, v. Sellers of Energy and Ancillary Services Into Markets Operated by the California Independent System Operator Corporation and the California Power Exchange, Respondent**

[Docket No. EL00-95-075]

**Investigation of Practices of the California Independent System Operator and the California Power Exchange and Puget Sound Energy, Inc., et al. Complainant, v. All Jurisdictional Sellers of Energy and/or Capacity at Wholesale into Electric Energy and/or Capacity Markets in the Pacific Northwest, Including Parties to the Western Systems Power Pool Agreement Respondent**

[Docket Nos. EL00-98-063, Docket No. EL01-10-007]

Pursuant to the orders issued on February 10, 2003., in the above captioned dockets,<sup>1</sup> the Commission has posted on its Web site (<http://www.ferc.gov>) the guidelines and templates for parties that will be making additional submissions. This information can be found in the "What's New at FERC" window.

All parties making these submissions must follow the posted instructions and use the provided templates for filing their executive summary and their indices of additional information.

Magalie R. Salas,  
Secretary.

[FR Doc. 03-4113 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. ER02-648-003, et al.]

**Sithe New Boston, LLC, et al.; Electric Rate and Corporate Filings**

February 12, 2003.

The following filings have been made with the Commission. The filings are

listed in ascending order within each docket classification.

**1. Sithe New Boston, LLC**

[Docket No. ER02-648-003]

Take notice that on February 10, 2003, Sithe New Boston, LLC filed a refund report in the above-captioned proceeding.

*Comment Date:* March 3, 2003.

**2. New England Power Pool ISO New England Inc.**

[Docket No. ER02-2330-009]

Take notice that on February 7, 2003, ISO New England Inc., submitted its notice in the above docket that the NEPOOL System Rules and computer programs necessary to implement New England's standard market design are fully in place and functional, a precondition to the effectiveness of the new markets, and that the ISO has advised the Commission that the current schedule calls for implementation of the new markets on March 1, 2003.

ISO New England, Inc., states that copies of said filing have been served upon NEPOOL Participants as well as upon the governors and utility regulatory agencies of the six New England States.

*Comment Date:* February 24, 2003.

**3. Union Power Partners, L.P.**

[Docket No. ER03-275-001]

Take notice that on February 10, 2003., Union Power Partners, L.P., (UPP) tendered for filing with the Federal Energy Regulatory Commission (Commission) an amendment to its filing submitted December 13, 2002 requesting to amend the Western Systems Power Pool (WSPP) Agreement to include UPP as a participant. UPP requests that the Commission allow the amendment to the WSPP Agreement to become effective on December 11, 2002.

UPP states that a copy of this filing has been served upon the WSPP Executive Committee Chair, WSPP Operating Committee Chair, WSPP General Counsel, and Arizona Public Service Company.

*Comment Date:* March 3, 2003.

**4. Ameren Services Company**

[Docket No. ER03-464-001]

Take notice that on February 7, 2003, Ameren Services Company (ASC) tendered for filing an unexecuted Service Agreement for Network Integration Transmission Service between ASC and Soyland Power Cooperative, Inc. ASC asserts that the purpose of the Agreement is to replace the unexecuted Agreement in Docket No. ER03-464-000 with a revised, unexecuted Agreement.

*Comment Date:* February 28, 2003.

**5. Ohio Valley Electric Corporation**

[Docket No. ER03-511-000]

Take notice that on February 10, 2003, Ohio Valley Electric Corporation (OVEC) tendered for filing a Notice of Cancellation of the Non-Firm Point-to-Point Transmission Service Agreement, dated as of October 23, 1996, between OVEC and Western Power Services, Inc. (WPS), designated as Service Agreement No. 2 under OVEC's FERC Electric Tariff, Original Volume No. 1. OVEC proposes an effective date of April 8, 2002.

OVEC states that a copy of this filing was served upon Western.

*Comment Date:* March 3, 2003.

**6. CL Power Sales Six, L.L.C.**

[Docket No. ER03-512-000]

Take notice that on February 10, 2003., CL Power Sales Six, L.L.C., tendered for filing a Notice of Cancellation of its authorization to engage in wholesale electric energy transactions at market-based rates, filed on August 7, 1996.

*Comment Date:* March 3, 2003.

**7. Invenenergy Energy Marketing LLC**

[Docket No. ER03-513-000]

Take notice that on February 10, 2003., Invenenergy Energy Marketing LLC (Invenenergy) filed a Notice of Cancellation of its FERC Electric Tariff, Original Volume No. 1, with a proposed effective date of October 1, 2002. Invenenergy states that it no longer engaged in the power marketing business, will not conduct power marketing activities in the future, and has no outstanding power sales contracts; accordingly, Invenenergy states that no purchasers will be affected by the Notice of Cancellation.

*Comment Date:* March 3, 2003.

**8. Duke Energy Marketing Corp.**

[Docket No. ER03-514-000]

Take notice that, on February 10, 2003, Duke Energy Marketing Corp., tendered for filing a Notice of Cancellation pursuant to 18 CFR 35.15, in order to reflect the cancellation of its market-based rate tariff, designated as Rate Schedule FERC No. 1, Revision No. 1, originally accepted for filing in Docket No. ER96-109-000.

*Comment Date:* March 3, 2003.

**9. Black Oak Capital, LLC**

[Docket No. ER03-515-000]

Take notice that on February 10, 2003, Black Oak Capital, LLC (Black Oak) petitioned the Federal Energy Regulatory Commission (Commission)

<sup>1</sup> San Diego Gas & Elec. Co. v. Sellers of Energy and Ancillary Serv., et al., 102 FERC ¶ 61,164 (2003), and Puget Sound Energy, Inc., et al., 102 FERC ¶ 61,163 (2003).

for acceptance of Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

Black Oak states that it intends to engage in wholesale electric power and energy purchases and sales as a marketer; is not in the business of generating or transmitting electric power; and, is an independent electricity marketer with a sole purpose of buying and selling electricity in the wholesale electricity market.

*Comment Date:* March 3, 2003.

#### 10. Florida Keys Electric Cooperative Association, Inc.

[Docket No. ES03-24-000]

Take notice that on February 6, 2003, Florida Keys Electric Cooperative Association, Inc. (Florida Keys) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to make short-term borrowings in an amount not to exceed \$8.7 million under agreements with CoBank, ACB and the National Rural Cooperative Finance Corporation.

Florida Keys also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

*Comment Date:* March 5, 2003.

#### Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659. Protests and interventions may be filed electronically

via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4114 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Application Tendered for Filing with the Commission, Soliciting Additional Studies Requests, Establishing Procedural Schedule for Licensing, and a Deadline for Submission of Final Amendments

February 13, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- a. *Type of Application:* Original Major License, constructed project.
- b. *Project No.:* 11810-004.
- c. *Date Filed:* January 30, 2003.
- d. *Applicant:* City of Augusta.
- e. *Name of Project:* Augusta Canal Project.

f. *Location:* Adjacent to the Savannah River, in Richmond County, Georgia, near the town of Augusta, Georgia. The project does not occupy Federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)-825(r).

h. *Applicant:* Max Hicks, Director, Utilities Department, 360 Bay Street, Suite 180, Augusta, Georgia 30901, (706) 312-4121.

i. *FERC Contact:* Monte TerHaar, (202)-502-6035 or [monte.terhaar@ferc.gov](mailto:monte.terhaar@ferc.gov).

j. *Cooperating agencies:* We are asking Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperation status should follow the instruction for filing comments described in item l below.

k. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the

Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant. Parties who would like to request additional scientific studies should follow the instruction for filing comments described in item l below.

l. *Deadline for filing comments on the application:* 60 days from date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's rules of practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filing. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (<http://www.ferc.gov>) under the "e-Filing" link. After logging into the e-Filing system, select "Comment on Filing" from the Filing Type Selection screen and continue with the filing process."

m. This application is not ready for environmental analysis at this time.

n. *The proposed project description:* The City of Augusta does not propose to construct hydroelectric generation facilities and the project would produce no power. Augusta is proposing to license parts of the Augusta Canal system which pass flows for use by three existing hydroelectric projects located in the Augusta Canal. These projects are the 1.2 megawatt (MW) Enterprise Project (No. 2935), the 2.475 MW Sibley Mill Project (No. 5044), and the 2.05 MW King Mill Project (No. 9988). The proposed project would consist of the following: (1) The 1,666-foot-long stone-masonry Augusta Diversion Dam; (2) the 2,250-foot-long Savannah River impoundment between Steven's Creek Dam and the Augusta Diversion Dam; and (3) the first level of the Augusta Canal, which extends about 7 miles between the Augusta Diversion Dam and the Thirteenth Street gates.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding

the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659. A copy is also available for inspection and reproduction at the address in item h above.

p. With this notice, we are initiating consultation with the Georgia State Historic Preservation Officer as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR, part 800.

q. *Procedural schedule:* At this time we do not anticipate the need for preparing a draft EA. We intend to prepare one, multi-project environmental document which will include the Augusta Canal Project (P-11810), the Enterprise Project (P-2935), and the Sibley Mill Project (P-5044). The EA will include our recommendations for operating procedures and environmental enhancement measures that should be part of any license issued by the Commission. Recipients will have 60 days to provide the Commission with any written comments on the EA. All comments filed with the Commission will be considered in the Order taking final action on the license applications. However, should substantive comments requiring re-analysis be received on the NEPA document, we would consider preparing a subsequent NEPA document.

The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

#### Scoping Document 1—March 2003.

Comments on Scoping Document 1—May 2003.

Issue acceptance letter/request additional information—May 2003.

Additional Information Due—July 2003.

Notice of ready for environmental analysis/Notice soliciting final terms and conditions—July 2003.

Deadline for Agency Recommendations—September 2003.

Notice of the availability of the EA—November 2003.

Public Comments on EA due—January 2003.

Ready for Commission's decision on the application—March 2004

r. Final amendments to the application must be filed with the Commission no later than 30 days from

the issuance date of the notice of ready for environmental analysis.

**Magalie R Salas,**

*Secretary.*

[FR Doc. 03-4118 Filed 2-19-03; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Application Accepted for Filing and Soliciting Motions to Intervene and Protests and Establishing Procedures for Relicensing

February 13, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* New Major License.

b. *Project No.:* 1979-012.

c. *Date Filed:* June 21, 2002.

d. *Applicant:* Wisconsin Public Service Corporation.

e. *Name of Project:* Alexander Hydroelectric Project.

f. *Location:* On the Wisconsin River near the City of Merrill, Lincoln County, Wisconsin. The project occupies 3.59 acres of public land administered by the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)—825(r).

h. *Applicant Contact:* Mr. David W. Harpole, Wisconsin Public Service Corporation, 700 N. Adams Street, PO Box 19002, Green Bay, Wisconsin. 54307 (920) 433-1264.

i. *FERC Contact:* Michael Spencer, [michael.spencer@FERC.fed.us](mailto:michael.spencer@FERC.fed.us), (202) 502-6093.

j. *Deadline for filing motions to intervene and protests:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie Salas, Secretary Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

The Commission's rules of practice and procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments

or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Status of environmental analysis:* This application is not ready for environmental analysis at this time.

l. *Description of Project:* The existing project consists of: (1) A dam, described from east to west side as comprised of a gated spillway controlled by 11 Taintor gates each measuring 26-foot-wide and 15-foot-high, the powerhouse, a 385-foot-long concrete wall with earth backfill, and a 515-foot-long, 20-foot-high earthen embankment dam; (2) a reservoir with a surface area of 803 acres and, a 7,000 acre-foot storage volume at normal pond elevation; (3) the powerhouse contains three generating units with an total installed capacity of 4,200-kilowatts (4) a transmission substation; and (5) appurtenant facilities. The applicant estimates that the average annual generation is 23,550 megawatt-hours.

m. *Locations of the application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866)208-3676, or for TTY, contact (202)502-8659. A copy is also available for inspection and reproduction at the address in item h above.

n. *Procedural schedule:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made if the Commission determines it necessary to do so.

Issue Scoping Document 1 for comments—March 2003.

Request Additional Information—May 2003.

Issue Scoping Document 2—August 2003.

Notice of application is ready for environmental analysis—August 2003.

Notice of the availability of the draft EA—December 2003.

Notice of the availability of the final EA—April 2004.

Ready for Commission's decision on the application—April 2004.

o. This notice also consists of the following standard paragraphs:

Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with

the requirements of rules of practice and procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

**Filing and Service of Responsive Documents**—All filings must (1) Bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03-4119 Filed 2-19-03; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Application Tendered for Filing with the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

February 13, 2003.

Take notice that the following hydroelectric subsequent license application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New License for a Major Water Power Project.

b. *Project No.:* P-2181-014.

c. *Date filed:* February 10, 2003.

d. *Applicant:* Northern States Power Company (d/b/a Xcel Energy).

e. *Name of Project:* Menomonie Hydroelectric Project.

f. *Location:* On the Red Cedar River, City of Menomonie, Dunn County, Wisconsin. This project would not use federal lands and there are no federal lands within the project's boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)—825(r).

h. *Applicant Contact:* Mr. William Zawacki, Director, Hydro Plants, or Ms. Kristina Bourget, Esq., Northern States Power Company (d/b/a Xcel Energy), 1414 West Hamilton Avenue, PO Box 8, Eau Claire, Wisconsin 54702-0008, 715-836-1136 or 715-839-1305, respectively, or Mr. William J. Madden, Jr., Esq., Winston and Strawn, 1400 L Street, NW., Washington, DC 20005-3502, 202-371-5715.

i. *FERC Contact:* John Ramer, [john.ramer@ferc.gov](mailto:john.ramer@ferc.gov) (202) 502-8969.

j. *Cooperating Agencies:* We are asking Federal, state, and local agencies and Indian tribes with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in item k below.

k. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an factual basis for complete analysis of the application on its merit, the resource agency, Indian tribe, or person must file a request for a study with the Commission not later than 60 days after the application filing (i.e., by April 10, 2003.) and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* April 10, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's rules of practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filing. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (<http://www.ferc.gov>) under the "e-Filing" link. After logging into the e-Filing system, select "Comment on Filing" from the Filing Type Selection screen and continue with the filing process."

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The Menomonie Hydroelectric Project consists of the following existing facilities: (1) A 624-foot-long by about 40-foot-high dam, topped with five, 40-foot-wide by 19-foot-high and one, 9-foot-high by 25-foot-wide, steel Tainter gates and with a total dam discharge capacity of 62,000 cubic feet per second (cfs); (2) a 1,405-acre reservoir (Lake Menomin) with a gross storage capacity of about 15,000-acre feet; (3) a 72-foot-long by about 50-foot-wide by 40-foot-high powerhouse containing two, vertical-shaft Kaplan turbine-generators with a combined total maximum hydraulic capacity of 2,700 cfs and with a total installed generating capacity of about 5.4 megawatts (MW) and producing a total of 23,358,292 kilowatt-hours (kWh) annually; (4) a substation containing a 69 kilovolt (kV) bus from which power flows to serve the applicant's interconnected electrical system or to a 12.5 kv local distribution system; along with (5) appurtenant facilities, such as, governors and electric switchgear. The dam and existing project facilities are owned by Northern States Power Company (d/b/a Xcel Energy).

o. A copy of the application is on file with the Commission and is available for public inspection. This filing may also be viewed on the web at <http://www.ferc.gov> using the "FERRIS" link—select "Docket #" and follow the instructions. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll free at (866) 208-3676 or for TTY, contact (202) 502-8659. A copy is also available for inspection and reproduction at the address in item h above.

p. With this notice, we are initiating consultation with the Wisconsin State Historic Preservation Officer (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. *Procedural schedule and final amendments:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate. The Commission staff proposes to issue one environmental assessment rather than issue a draft and final EA. Comments, terms and conditions, recommendations, prescriptions, and reply comments, if any, will be addressed in an EA issued in the spring of 2004.

Issue Acceptance or Deficiency Letter—June 2003.

Issue Scoping Document—July 2003.

Notice that application is ready for environmental analysis—October 2003.  
Notice of the availability of the EA—March 2004.

Ready for Commission decision on the application—May 2004.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–4120 Filed 2–19–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Application Tendered for Filing with the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

February 13, 2003.

Take notice that the following hydroelectric subsequent license application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New License for a Major Water Power Project.

b. *Project No.:* P–2697–014.

c. *Date filed:* February 10, 2003.

d. *Applicant:* Northern States Power Company (d/b/a Xcel Energy).

e. *Name of Project:* Cedar Falls Hydroelectric Project.

f. *Location:* On the Red Cedar River, Dunn County, Wisconsin. This project would not use federal lands; however, a 2.4 acre island owned by the Bureau of Land Management located at the confluence of Red Cedar River and Tainter Lake is within the project's boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Mr. William Zawacki, Director, Hydro Plants, or Ms. Kristina Bourget, Esq., Northern States Power Company (d/b/a Xcel Energy), 1414 West Hamilton Avenue, PO Box 8, Eau Claire, Wisconsin 54702–0008, 715–836–1136 or 715–839–1305, respectively, or Mr. William J. Madden, Jr., Esq., Winston and Strawn, 1400 L Street, NW., Washington, DC 20005–3502, 202–371–5715.

i. *FERC Contact:* John Ramer, john.ramer@ferc.gov (202) 502–8969.

j. *Cooperating Agencies:* We are asking Federal, state, and local agencies and Indian tribes with jurisdiction and/

or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in item k below.

k. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an factual basis for complete analysis of the application on its merit, the resource agency, Indian tribe, or person must file a request for a study with the Commission not later than 60 days after the application filing (*i.e.*, by April 10, 2003.) and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* April 10, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's rules of practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filing. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (<http://www.ferc.gov>) under the "e-Filing" link. After logging into the e-Filing system, select "Comment on Filing" from the Filing Type Selection screen and continue with the filing process."

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The Cedar Falls Hydroelectric Project consists of the following existing facilities: (1) A 510-foot-long by about 50-foot-high dam, topped with two, 23-foot-wide by 5-foot-high, steel Tainter gates and with a total dam discharge capacity of 57,000 cubic feet per second (cfs); (2) a 1,752-acre reservoir (Tainter Lake) with a gross storage capacity of about 23,000-acre feet; (3) a 140-foot-long by 150-foot-wide by 42-foot-high powerhouse containing three 2,000 kilowatt (kW) horizontal generators with Francis turbines with a total maximum hydraulic capacity of 2,500 cfs and with a total installed

generating capacity of 7.1 megawatts (MW) and producing a total of 33,678,351 kilowatt-hours (kWh) annually; (4) a substation containing a 69 kilovolt (kV) bus from which power flows to four 69 kV transmission lines which serve the applicant's interconnected electrical system or to a 10,500 kva transformer that serves a local distribution load; along with (5) appurtenant facilities, such as, governors and electric switchgear. The dam and existing project facilities are owned by Northern States Power Company (d/b/a Xcel Energy).

o. A copy of the application is on file with the Commission and is available for public inspection. This filing may also be viewed on the web at <http://www.ferc.gov> using the "FERRIS" link—select "Docket #" and follow the instructions. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll free at (866) 208–3676 or for TTY, contact (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

p. With this notice, we are initiating consultation with the Wisconsin State Historic Preservation Officer (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. *Procedural schedule and final amendments:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate. The Commission staff proposes to issue one environmental assessment rather than issue a draft and final EA. Comments, terms and conditions, recommendations, prescriptions, and reply comments, if any, will be addressed in an EA issued in the spring of 2004.

Issue Acceptance or Deficiency Letter, June 2003.

Issue Scoping Document, July 2003.

Notice that application is ready for environmental analysis, October 2003.

Notice of the availability of the EA, March 2004.

Ready for Commission decision on the application, May 2004.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–4121 Filed 2–19–03; 8:45 am]

BILLING CODE 6717–01–P

**FEDERAL MARITIME COMMISSION****Notice of Agreement(s) Filed**

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the Federal Register.

Agreement No.: 011409-008

Title: Transpacific Carrier Services, Inc. Agreement

Parties: Westbound Transpacific Stabilization Agreement; Transpacific Space Utilization Agreement; Asia North America Eastbound Rate Agreement; Transpacific Stabilization

Agreement; American President Lines, Ltd.; APL Moller-Maersk Sealand; China Shipping Container Lines Co., Ltd.; CMA CGM, S.A.; COSCO Container Lines Company, Ltd.; Evergreen Marine Corporation; Hanjin Shipping Co., Ltd.; Hapag-Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha, Ltd.; Orient Overseas Container Line, Inc.; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; and Yangming Lines

Synopsis: The amendment adds China Shipping Container Lines Co., Ltd. as a party to the agreement.

By Order of the Federal Maritime Commission

**Bryant L. VanBrakle,**

*Secretary.*

[FR Doc. 03-4142 Filed 2-19-03; 8:45 am]

**BILLING CODE 6730-01-P**

**FEDERAL MARITIME COMMISSION****Ocean Transportation Intermediary License Reissuances**

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR 515.

License No.	Name/Address	Date reissued
17310N .....	J.M.C. Transport Corporation., 9133 South La Cienega Blvd. #120, Inglewood, CA 90301 .....	December 8, 2002.
17151N .....	Ultra Air Cargo, Inc., 555 S. Isis Avenue, Inglewood, CA 90301 .....	November 1, 2002.
3883F .....	Brye International, Inc., 108 South Franklin Avenue Suite 15, Valley Stream, NY 11580 .....	December 3, 2002.
4175NF .....	Silken Fortress Corporation, dba Transcargo International, 5858 S. Holmes Avenue, Los Angeles, CA 90001.	December 8, 2002.

**Sandra L. Kusumoto,**

*Director, Bureau of Consumer Complaints and Licensing.*

[FR Doc. 03-4144 Filed 2-19-03; 8:45 am]

**BILLING CODE 6730-01-P**

Reason : Surrendered license voluntarily.

**Sandra L. Kusumoto,**

*Director, Bureau of Consumer Complaints and Licensing.*

[FR Doc. 03-4143 Filed 2-19-03; 8:45 am]

**BILLING CODE 6730-01-P**

**FEDERAL MARITIME COMMISSION****Ocean Transportation Intermediary License Revocations**

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number : 4217F

Name : Reliable Van & Storage Co., Inc.  
Address : 550 Division Street, Elizabeth, NJ 07201

Date Revoked : January 15, 2003.

Reason : Failed to maintain a valid bond.

License Number : 17151F

Name : Ultra Air Cargo Inc.  
Address : 555 S. Isis Avenue,  
Inglewood, CA 90301

Date Revoked : November 1, 2002.

**GENERAL SERVICES ADMINISTRATION****Notice of Web Site Location for Annual Motor Vehicle Reports**

**AGENCY:** General Services Administration (GSA).

**SUMMARY:** Under the provisions of the Energy Policy Act of 1992, as amended, and the reporting obligations under 42 U.S.C. 13218(b), GSA hereby provides, for public review, access to annual reports covering motor vehicle acquisitions beginning with the year 1999. Each report details the fuel type, vehicle classification and number of vehicles required in the covered fiscal year. These reports are accessible on the agency's Web site located at <http://www.gsa.gov/fleetreports>.

**FOR FURTHER INFORMATION CONTACT:** John Hughes, Administrative Management Division (CAI), GSA (202) 501-2162.

Dated: February 13, 2003.

**Daniel K. Cooper,**

*Director, Administrative Management Division.*

[FR Doc. 03-4052 Filed 2-19-03; 8:45 am]

**BILLING CODE 6820-FM-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary****Findings of Scientific Misconduct**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Office of the Secretary, HHS, published a notice in the **Federal Register** of January 2, 2003, concerning a finding of scientific misconduct regarding Dr. Ganz. The document contained the incorrect middle initial of Dr. Ganz.

**FOR FURTHER INFORMATION CONTACT:** Director, Division of Investigative Oversight, Office of Research Integrity, (301) 443-5330.

**Correction**

In the **Federal Register** of January 2, 2003, in FR Doc. 02-33079, on page 123, in the third column, first paragraph,



correct the name of Michael E. Ganz, M.D. to read: Michael B. Ganz, M.D.

Dated: February 13, 2003.

**Chris B. Pascal,**

*Director, Office of Research Integrity.*

[FR Doc. 03-4088 Filed 2-19-03; 8:45 am]

BILLING CODE 4150-31-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-191]

#### Public Health Assessments Completed

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces those sites for which ATSDR has completed public health assessments during the period from October 2002 through December 2002. This list includes sites that are on or proposed for inclusion on the National Priorities List (NPL), and includes sites for which assessments were prepared in response to requests from the public.

**FOR FURTHER INFORMATION CONTACT:** Robert C. Williams, P.E., DEE, Assistant Surgeon General, Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E-32, Atlanta, Georgia 30333, telephone (404) 498-0007.

**SUPPLEMENTARY INFORMATION:** The most recent list of completed public health assessments was published in the **Federal Register** on December 4, 2002 (67 FR 72216). This announcement is the responsibility of ATSDR under the regulation, Public Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities (42 CFR part 90). This rule sets forth ATSDR's procedures for the conduct of public health assessments under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604(i)).

#### Availability

The completed public health assessments and addenda are available for public inspection at the Division of Health Assessment and Consultation, Agency for Toxic Substances and

Disease Registry, Building 1825, Century Blvd, Atlanta, Georgia (not a mailing address), between 8 a.m. and 4:30 p.m., Monday through Friday except legal holidays. The completed public health assessments are also available by mail through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, or by telephone at (703) 605-6000. NTIS charges for copies of public health assessments and addenda. The NTIS order numbers are listed in parentheses following the site names.

#### Public Health Assessments Completed or Issued

Between September 1, 2002 and December 31, 2002, public health assessments were issued for the sites listed below:

##### NPL Sites

##### Arkansas

Mountain Pine Pressure Treating (PB2003-100516).

##### Florida

Naval Air Station Cecil Field (a/k/a USN Air Station Cecil Field) (PB2003-101531).

##### Illinois

Lisle Residential Wells I (a/k/a Lockformer Company) (PB2003-100143).

##### Louisiana

Central Wood Preserving Company (PB2003-100517) Ruston Foundry (PB2003-100079).

##### New Hampshire

Gardner-Roussell Park and Dr. Norman W. Crisp Elementary School (a/k/a Dr. Crisp School/Gardner Roussell Park) (PB2003-100503).

##### New Jersey

Boeing Michigan Aeronautical Research Center/McGuire Missile (PB2003-100508).

McGuire Air Force Base #1 (PB2003-100509)

##### New York

Huntington Landfill (a/k/a Huntington Town Landfill) (PB2003-100504).

Peter Cooper-Markham (a/k/a Peter Cooper Corporation (MARKHAMS)) (PB2003-100154).

Smithtown Groundwater Contamination (a/k/a Smithtown Ground Water Contamination) (PB2003-100147).

##### Pennsylvania

Naval Air Warfare Center (a/k/a Naval Air Development Center (8 Waste Areas)) (PB2003-100510).

#### Non NPL Petitioned Sites

None

Dated: February 12, 2003.

**Georgi Jones,**

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 03-4026 Filed 2-19-03; 8:45 am]

BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 67, No. 125, pp. 43632-43633, dated Friday, June 28, 2002; Vol. 67, No. 207, p. 65589, dated Friday, October 25, 2002) is amended to reflect a change to the organizational structure of CMS by establishing the Office of Health Insurance Portability and Accountability Act Standards.

The specific amendments to part F are described below:

- Section F.10. (Organization) is amended to read as follows:
  1. Public Affairs Office (FAC)
  2. Center for Beneficiary Choices (FAE)
  3. Office of Legislation (FAF)
  4. Center for Medicare Management (FAH)
  5. Office of Equal Opportunity and Civil Rights (FAJ)
  6. Office of Research, Demonstration, and Information (FAK)
  7. Office of Clinical Standards and Quality (FAM)
  8. Office of the Actuary (FAN)
  9. Center for Medicaid and State Operations (FAS)
  10. Northeastern Consortium (FAU)
  11. Southern Consortium (FAV)
  12. Midwestern Consortium (FAW)
  13. Western Consortium (FAX)
  14. Office of Operations Management (FAY)
  15. Office of Internal Customer Support (FBA)
  16. Office of Information Services (FBB)
  17. Office of Financial Management (FBC)
  18. Office of Strategic Operations and Regulatory Affairs (FGA)
  19. Office of Health Insurance Portability and Accountability Act Standards (FHA)
- Section F.20. (Functions) is amended by deleting the functional



statement in its entirety for the Office of Operations Management. The new functional statement reads as follows:

#### **14. Office of Operations Management (FAY)**

- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.

- Prepares and presents recommendations to the Administrator, Deputy Administrator/COO and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

- Collaborates with appropriate CMS component(s) to collect and disseminate data on health care and insurance market trends that affect CMS' business risk profile. The Risk Management Staff has the lead for monitoring indicators of risk associated with the operations of CMS and our business partners.

- Surveys risk assessment techniques in use in the private and public sectors and identifies and applies the most useful ones for CMS. Helps develop new risk assessment techniques and keeps abreast of methodological developments in the professional literature.

- Promotes and teaches risk assessment methods to business owners throughout CMS. Promotes awareness of the importance of risk analysis as a component of business planning and trains CMS staff in specific techniques and their applicability in particular situations.

- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.

- Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.

#### *Specific Project Management Functions*

- Develops, in conjunction with staff in CMS centers and offices, major project plans, implementation schedules and post implementation evaluations.

- Promotes project planning principles throughout the Agency and

provides technical guidance to the Agency on project planning and management techniques.

- Reports to the COO and senior officials on progress of Agency priority projects. Negotiates with and supports project and component heads regarding project schedules, progress, etc.

- Prepares and presents recommendations to senior officials regarding major projects.

- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.

- Collaborates with the Risk Management Staff, Operational Review Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.

- Conducts process control analysis and tracking to ensure projects are running smoothly.

- Prepares and presents recommendations to the Administrator, Deputy Administrator/COO and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

#### *Specific Operational Review Functions*

- Identifies operational vulnerabilities in CMS and develops and executes an internal audit plan for each fiscal year, subject to approval by the Deputy Administrator and other senior leadership of CMS.

- Plans and conducts targeted internal audits and makes recommendations to strengthen internal audits and improve the operations of the Agency. The subjects of these reviews will be determined through regular periodic consultation with the Project Management Staff, Risk 3 Management Staff, the Director of the Office of Operations Management, and the Deputy Administrator. Drafts written reports summarizing conclusions and presents findings to appropriate officials for follow-up actions.

- Monitors the implementation of corrective actions relative to ORS recommendations, as well as those resulting from selected OIG/GAO audits to assure results and accountability.

- Reviews and evaluates enterprise-wide programs, projects, and processes to assess their effectiveness and efficiency, compliance with laws,

regulations, or adequacy of management processes.

- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.

- Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.

- Collaborates with the Risk Management Staff, Project Management Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.

- Serves as the Agency focal point for implementation of OMB Circular A-76 and Federal Activities Reform Act and Competitive Outsourcing Initiative.

- Coordinates the development of the Agency's submission to the OMB mandated Performance Assessment Rating Tool that links Agency program performance to the budget process. Serves as Agency liaison with the Department and OMB.

#### *Special Racial and Ethnic Health Initiatives Functions*

- Develops and sustains external contacts and partnerships regarding racial and ethnic health issues. Works collaboratively with the DHHS Office of Minority Health with responsibility for coordinating CMS activities with Departmental and White House initiatives that are directed by Executive Orders. Collaborates with the academic community, professional societies, civic, and social groups and non-government agencies concerning health problems of special populations.

- Provides direction in setting priorities, establishing goals and objectives, defining appropriate interventions, and assisting in determining evaluation tools for racial and ethnic health activities.

- Coordinates consolidated reporting on communication and educational activities targeting racial and ethnic populations.

#### *Faith-Based and Community Initiatives Functions*

- Coordinates a comprehensive effort to incorporate faith-based and other community organizations into CMS programs and initiatives.

- Develops and coordinates effective outreach and education efforts to

disseminate information regarding CMS programs, contracting opportunities, and other initiatives to faith-based and other community organizations.

#### 19. Office of Health Insurance Portability and Accountability Act Standards (FHA)

- Develops, implements and administers the enforcement of the Health Insurance Portability and Accountability Act (HIPAA) including portability, transactions, code sets, identifiers, and security.
- Develops, implements and administers the enforcement of the Administrative Simplification Compliance Act (ASCA).
- Develops regulations to enforce the provisions of the HIPAA and the ASCA. Also develops regulations and guidance materials on HIPAA standards.
- Educates and reaches out to the public and internal CMS staff on HIPAA issues. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquiries on HIPAA issues, and liaisons with industry representatives.
- Works with Federal departments and agencies to identify and adopt universal messaging and clinical health data standards, and represents CMS and HHS in national projects supporting the national health enterprise architecture and the National Health Information Infrastructure.
- Provides technical assistance regarding HIPAA standards and their implementation.
- Collaborates with the Department, especially the Office for Civil Rights, on HIPAA policy issues.
- Coordinates and provides guidance on legislative and regulatory issues.
- Provides assistance and guidance for HIPAA-related budget formulation and execution activities.
- Oversees the enforcement of the insurance portability provisions of HIPAA related to non-Federal governmental health plans and States.

Dated: November 21, 2002.

**Ruben J. King-Shaw, Jr.,**

*Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.*

[FR Doc. 03-4086 Filed 2-19-03; 8:45 am]

**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 02N-0259]

#### Agency Information Collection Activities; Announcement of OMB Approval; Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, "A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1"

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, "A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 18, 2002 (67 FR 64397), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0501. The approval expires on June 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 10, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-4090 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

#### Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 18, 2003, from 8 a.m. to 6 p.m.; and on March 19, 2003, from 8:30 a.m. to 3 p.m.

*Location:* U.S. Department of Agriculture, Animal and Plant Health Inspection Service, 4700 River Rd., Conference Center, Riverdale, MD, 301-734-8010.

*Contact Person:* Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1756, or FDA Advisory Committee Information Line, 1-800-741-8138 301-443-0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The meeting's purpose is to discuss the scientific issues and principles involved in assessing and evaluating *Enterobacter sakazakii* contamination in powdered infant formula, risk reduction strategies based on available data, and research questions and priorities. To ensure the presence of the most relevant expertise, the membership of the subcommittee, which has expertise in contaminants, will be augmented by consultants with expertise in infant formula.

The background material for this meeting will be posted on the Internet when available or one working day before the meeting at <http://www.cfsan.fda.gov/~lrd/vidtel.html>.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2003. Oral

presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on March 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jeanne E. Latham at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 10, 2003.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-4089 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Oncologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 12 and 13, 2003, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or email: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug applications approved under 21 CFR 314.500 (Subpart H, accelerated approval) in an open session on March 12 and 13, 2003, to: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. On March 12, 2003, the committee will discuss phase IV commitments of: (1) new drug application (NDA) 50-718 DOXIL (doxorubicin HCl, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of Kaposi's Sarcoma in acquired immune deficiency syndrome (AIDS) patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) NDA 50-718/S-006 DOXIL (Doxorubicin HCl, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of metastatic ovarian cancer in patients with disease that is refractory to both paclitaxel and platinum-based chemotherapy regimens; (3) biologics license application (BLA) 97-1325 ONTAK (deneluekin diftotox, Ligand Pharmaceuticals) for the treatment of persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor; and (4) NDA 20-221/S-002, ETHYOL injection (amifostine, MedImmune Oncology, Inc.) for reducing the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced nonsmall cell lung cancer. On March 13, 2003, the committee will discuss phase IV commitments of: (1) NDA 21-174, MYLOTARG (gemtuzumab ozogamicin, Wyeth-Ayerst Laboratories, Inc.) for the treatment of CD33 positive acute

myeloid leukemia in first relapse of patients who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy; (2) NDA 21-041, DEPOCYT (cytarabine, SkyePharma, Inc.) for the intrathecal treatment of lymphomatous meningitis; (3) NDA 21-156 CELEBREX (celecoxib, Pharmacia Corp.) indicated in the reduction in number of adenomatous colorectal polyps in familial adenomatous polyposis patients; and (4) NDA 21-029, TEMODAR (temozolomide, Schering Corp.) for the treatment of adult patients with refractory anaplastic astrocytoma.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. and 12:30 p.m. to 1 p.m. on both days. Time allotted for each presentation may be limited. Additional open public sessions may be conducted after the presentations for interested persons who have submitted their request to speak by March 3, 2003, to address issues specific to the topic before the committee. Those desiring to make formal oral presentations should notify the contact person before March 3, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Johanna Clifford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 10, 2003.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-4000 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT****[Docket No. FR-4820-N-04]****Notice of Proposed Information Collection: Comment Request; Fee or Roster Designation, HUD Conditions and Appraisal Report****AGENCY:** Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments Due Date: April 21, 2003.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or Wyne—Eddins@hud.gov.

**FOR FURTHER INFORMATION CONTACT:** Vance Morris, Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th SW., Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Fee or Roster Designation, HUD Conditions and Appraisal Report.

*OMB Control Number, if applicable:* 2502-0538.

*Description of the need for the information and proposed use:* This information is gathered from real estate appraisers seeking HUD acceptance. The information collection provides for a more thorough and complete appraisal of prospective HUD-insured single-family properties ensuring that mortgages are acceptable for FHA insurance and thereby protecting the interest of HUD and the taxpayers in the FHA insurance fund.

*Agency form numbers, if applicable:* HUD-92563, HUD-92564-VC, HUD-92564-HS, HUD-92564-CN, and Fannie Mae Forms 1004 and 1004B.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The estimated total number of hours needed to prepare the information collection is 576,720; the number of respondents is 16,440 generating 3,601,440 annual responses; the frequency per response is on occasion; and the estimated time needed to prepare the responses varies from 5 minutes to 30 minutes.

*Status of the proposed information collection:* Extension of a currently approved collection.

**Authority:** The paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: February 12, 2003.

**John C. Weicher,**

*Assistant Secretary for Housing-Federal Housing Commissioner.*

[FR Doc. 03-4038 Filed 2-19-03; 8:45 am]

**BILLING CODE 4210-27-M**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT****[Docket No. FR-4815-N-05]****Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request; Fair Housing Initiatives Program Application**

**AGENCY:** Office of the Chief Information Officer.

**ACTION:** Notice of proposed information collection.

**SUMMARY:** The proposed information collection requirement described below

has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments Due Date: March 6, 2003.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number) and should be sent to: Lauren Wittenberg, HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail: [Lauren.Wittenberg@omb.eop.gov](mailto:Lauren.Wittenberg@omb.eop.gov); fax: (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail [Wayne.Eddins@HUD.gov](mailto:Wayne.Eddins@HUD.gov); telephone (202) 708-2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

**SUPPLEMENTARY INFORMATION:** This Notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, a proposed revision to the currently approved information collection for selecting applicants for the Fair Housing Initiatives (FHIP) Program grants.

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*This Notice also lists the following information:*

*Title of Proposal:* Fair Housing Initiatives Program Application.

*Description of Information Collection:* This is a revision to the currently

approved information collection for selecting applicants for the Fair Housing Initiatives (FHIP) Program grants which will be part of the 2003 Notice of Funding Availability (NOFA). These grants are to fund fair housing enforcement and/or education and outreach activities under the following initiatives: Administrative Enforcement; Private Enforcement; Education and Outreach; and Fair Housing Organizations. Proposed revisions to the currently approved collections would include a certification requirement that FHIP funds will not be used to settle a claim, satisfy a judgment, or fulfill a court order in any defensive litigation or that key project personnel have no prior felony convictions or convicted of crimes involving fraud or perjury; descriptions of how program activities will support HUD goals, identify performance measures/outcomes in support of these goals, and identify baseline conditions and target levels of the performance measures that each applicant plans to achieve in reports submitted to HUD. It would also require the submission of two budgets: at 80 percent funding level and at 100 percent funding level.

*OMB Control Number:* 2529-0033.

*Agency Form Numbers:* HUD forms 40076-FHIP, 424, 424B, 424C, 424CB, 424CBW, 2880, 2990, 2991, 2993, 2994, and OMB SF LLL.

*Members of Affected Public:* Not-for-profit institutions, State, Local or Tribal Government, Business or other for-profit.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of responses, and hours of response:* An estimation of the total number of hours needed to prepare the information collection is 28,220, number of respondents is 400 frequency response is 4 per annum, and the total hours per respondent is 100.5.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: February 13, 2003.

**Wayne Eddins,**

*Departmental Reports Management Officer,  
Office of the Chief Information Officer.*

[FR Doc. 03-4036 Filed 2-19-03; 8:45 am]

**BILLING CODE 4210-72-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4558-N-11]

### Mortgagee Review Board; Administrative Actions

**AGENCY:** Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** In accordance with section 202(c) of the National Housing Act, this document provides notice of the cause and description of administrative actions taken by HUD's Mortgagee Review Board against HUD-approved mortgagees.

**FOR FURTHER INFORMATION CONTACT:** D. Jackson Kinkaid, Secretary to the Mortgagee Review Board, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708-3041, extension 3574 (this is not a toll-free number). A telecommunications device for hearing and speech-impaired individuals is available at 1-800-877-8339 (Federal Information Relay Service).

**SUPPLEMENTARY INFORMATION:** Section 202(c)(5) of the National Housing Act (added by section 142 of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved December 15, 1989), requires that HUD "publish a description of and the cause for administrative action against a HUD-approved mortgagee" by HUD's Mortgagee Review Board. In accordance with the requirements of section 202(c)(5), notice is given of administrative actions that have been taken by the Mortgagee Review Board from January 1, 2002, through March 31, 2002.

#### 1. Allied Financial Services, Inc., Birmingham, AL

[Docket No. 00-1344-MR]

**Action:** In a letter dated December 13, 2000, the Board withdrew HUD's approval, specifically, the approval of the Federal Housing Administration (HUD/FHA), of Allied Financial Services, Inc.'s (AFS) approval for three years. The Board also voted to impose a civil money penalty.

**Cause:** The Board took this action based on the following violations of HUD/FHA requirements: AFS failed to file annual loan origination reports for 1997-1999, which supplements the requirements of the Home Mortgage Disclosure Act; AFS used false documentation to originate a HUD/FHA loan; AFS failed to ensure that only AFS employees process HUD/FHA loans; AFS employed a loan officer who was

not an exclusive employee; and AFS failed to provide complete loan origination files and/or documents for review.

#### 2. Custom Mortgage Corporation, San Antonio, TX

[Docket No. 01-1543-MR]

**Action:** Settlement Agreement signed January 11, 2002. Without admitting fault or liability, Custom Mortgage Corporation (CMC) agreed to pay a civil money penalty.

**Cause:** The Board took this action based on the following violations of HUD/FHA requirements: CMC failed to maintain and implement a Quality Control Plan in compliance with HUD/FHA requirements; CMC accepted eleven loans originated by personnel not employed by CMC; and CMC paid fees and compensation to unauthorized individuals in connection with nine loans.

#### 3. Fidelity Mortgage & Funding Co., Memphis, TN

[Docket No. 01-1415-MR]

**Action:** In a letter dated February 12, 2002, the Board withdrew the HUD/FHA approval of Fidelity Mortgage & Funding Co. (Fidelity) approval for five years. In addition, the Board voted to impose a civil money penalty.

**Cause:** The Board took these actions based on the following findings of violations of HUD/FHA requirements: In 106 loans, Fidelity allowed non-employees to participate in the origination of loans to be insured by HUD/FHA; and Fidelity failed to develop, maintain, and implement a Quality Control Plan that meets HUD guidelines.

#### 4. First Mortgage of Indiana, Inc., Indianapolis, IN

[Docket No. 99-1031-MR]

**Action:** Settlement Agreement signed January 30, 2002. Without admitting fault or liability, First Mortgage of Indiana, Inc. (FMI) agreed to pay a civil money penalty.

**Cause:** The Board took this action based on the following violations of HUD/FHA requirements: FMI failed to maintain and implement a Quality Control Plan in compliance with HUD/FHA requirements; and FMI charged certain fees which were not allowed; and FMI used a rubber stamp to sign the Lender's Certification on page four of HUD Form 92900-A prior to closing.

#### 5. Golden Empire Mortgage, Inc., Bakersfield, CA [Docket No. 98-853-MR]

**Action:** Settlement Agreement was signed March 26, 2002. Without

admitting fault or liability, Golden Empire Mortgage, Inc. (GEM) agreed to pay a civil money penalty. In addition, GEM agreed to indemnify HUD for any losses incurred on 12 loans.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: GEM failed to notify HUD of violations which were discovered by GEM's own quality control review; GEM failed to notify HUD that certain fraudulent documents were discovered during GEM's quality control review; GEM permitted straw buyers to qualify for HUD/FHA insured mortgages; GEM failed to require that all borrowers meet their required investment; GEM failed to correctly calculate the borrower's income in certain loans; and GEM failed to require that all repairs and/or valuation conditions were satisfied.

**6. Jack Johnson and Associates, Inc., d/b/a Home Equity Mortgage, Riverside, CA**

[Docket No. 00-1348-MR]

*Action:* Settlement Agreement signed February 7, 2002. The Board withdrew the HUD/FHA approval of JJAI for a period of five years. Without admitting fault or liability, Jack Johnson and Associates, Inc. (JJAI), doing business as (d/b/a) Home Equity Mortgage agreed to pay a civil money penalty.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: JJAI failed to file annual loan origination reports for 1992-1999, which supplements the requirements of the Home Mortgage Disclosure Act; JJAI failed to maintain and implement a quality control plan in compliance with HUD requirements; JJAI permitted an investor to circumvent the restrictions on FHA insured loans to investors; JJAI permitted false information to be used in originating loans and obtaining HUD/FHA mortgage insurance; and JJAI allowed non-employees to take loan applications for three FHA-insured loans.

**7. Pac West Financial Corporation, Ontario, CA**

[Docket No. 01-1406-MR]

*Action:* Settlement Agreement signed January 11, 2002. Without admitting fault or liability, Pac West Financial Corporation (PWF) agreed to pay a civil money penalty. In addition, PWF agreed to indemnify HUD for any losses incurred on eight loans.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: PWF failed to maintain and implement a Quality Control Plan in compliance with HUD

requirements; PWF failed to file annual reports regarding loan activity; PWF used falsified documentation and/or conflicting information in originating 8 loans and obtaining HUD/FHA mortgage insurance; PWF allowed mortgagors to sign loan documents in blank form in two cases; and PWF failed to ensure that gift letters met HUD requirements in 18 loans.

**8. Ron Simpson & Associates d/b/a Rockwell Mortgage Company, Farmington Hills, MI**

[Docket No. 011497-MR]

*Action:* Settlement Agreement signed March 7, 2002. Without admitting fault or liability, Ron Simpson & Associates, d/b/a Rockwell Mortgage Company (RMC), agreed to pay a civil money penalty.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: RMC employed loan officers who were not exclusive employees; RMC failed to implement and maintain a Quality Control Plan in complete conformity with HUD/FHA requirements; RMC failed to maintain complete origination files and; RMC charged borrowers fees not permitted by HUD.

**9. Southern Mortgage Investment Corporation, Winter Park, FL**

[Docket No. 01-1480-MR]

*Action:* In a letter dated May 8, 2002, the Board withdrew the HUD/FHA approval of Southern Mortgage Investment Corporation (SMIC) approval for three years. In addition, they agreed to pay a civil money penalty.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: SMIC failed to establish and maintain a Quality Control Plan for the origination of HUD/FHA insured mortgages; SMIC allowed the handling of loan documents by an interested third party; and SMIC failed to maintain complete loan files.

**10. Underline, Inc., d/b/a Advantage Mortgage Services, Santa Ana, CA**

[Docket No. 01-1604-MR]

*Action:* Settlement Agreement was signed on March 20, 2002. Without admitting fault or liability, Underline, Inc.(UI) d/b/a/ Advantage Mortgage Services agreed to pay a civil money penalty.

*Cause:* The Board took this action based on the following violations of HUD requirements: UI allowed non-employees to originate HUD/FHA insured loans, and UI failed to implement a Quality Control Plan in

compliance with HUD requirements by allowing non-employees to originate HUD/FHA insured loans.

**11. Utah Mortgage Loan Corporation, Midvale, UT**

[Docket No. 00-1342-MR]

*Action:* Settlement Agreement letter was signed February 9, 2002. Without admitting fault or liability, Utah Mortgage Loan Corporation (UMLC) agreed to pay a civil money penalty.

*Cause:* The Board took this action based on the following violations of HUD/FHA requirements: UMLC failed to maintain and implement a Quality Control Plan in compliance with HUD requirements; UMLC permitted non-UMLC employees to originate FHA loan applications; UMLC failed to pay the operating expenses of an employee; UMLC paid unallowable fees/compensation in connection with HUD/FHA insured mortgages to non-employees; UMLC paid origination commissions to UMLC Direct Endorsement Underwriter who also performed the Quality Control Audits on HUD/FHA loans; and UMLC leased office space to another entity that was not physically separate and apart from UMLC.

Dated: February 6, 2003.

**John C. Weicher,**

*Assistant Secretary for Housing-Federal Housing Commissioner, Chairman, Mortgagee Review Board.*

[FR Doc. 03-4037 Filed 2-19-03; 8:45 am]

**BILLING CODE 4210-27-P**

**DEPARTMENT OF INTERIOR**

**Fish and Wildlife Service**

**Notice of Intent To Prepare a Comprehensive Conservation Plan and Environmental Assessment for Agassiz National Wildlife Refuge in Northwestern Minnesota.**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of intent.

**SUMMARY:** This notice advises the public that the U.S. Fish and Wildlife Service (Service) intends to gather information necessary to prepare a Comprehensive Conservation Plan (CCP) and Environmental Assessment (EA) pursuant to the National Environmental Policy Act (NEPA) and its implementing regulations, for the Agassiz National Wildlife Refuge located in Marshall County, Minnesota.

The Service is furnishing this notice in compliance with the National Wildlife Refuge System Administration

Act of 1966, as amended (16 U.S.C. 668dd *et seq.*), to achieve the following:

- (1) Advise other agencies and the public of our intentions, and
- (2) Obtain additional suggestions and information on the scope of alternatives and impacts to be considered.

Open house style meetings and focus group meetings will also be held throughout the scoping phase of the CCP development process. In addition, the Service is inviting comments on archaeological, historic, and traditional cultural sites in accordance with the National Historic Preservation Act.

Special mailings, newspaper articles, and other media announcements will inform people of the opportunities for written input throughout the CCP planning process. Information on the CCP planning process will be posted on the Internet at <http://www.midwest.fws.gov/planning/agassiz.htm>

**ADDRESSES:** Address comments to Refuge Manager, Agassiz National Wildlife Refuge, 22996 290th Street NE., Middle River, MN 56737. Comments may also be submitted electronically at [r3planning@fws.gov](mailto:r3planning@fws.gov).

**FOR FURTHER INFORMATION CONTACT:** Refuge Manager, Agassiz National Wildlife Refuge, Phone: (218)-449-4115.

**SUPPLEMENTARY INFORMATION:** By Federal Law, all lands within the National Wildlife Refuge System are to be managed in accordance with an approved CCP. The CCP guides management decisions and identifies refuge goals, long-range objectives, and strategies for achieving refuge purposes.

The CCP planning process will consider many elements, including wildlife and habitat management, habitat protection and acquisition, wilderness preservation, public recreational activities, industrial use, and cultural resource preservation. Public input into this planning process is essential.

The CCP will provide other agencies and the public with a clear understanding of the desired conditions for the Refuge and how the Service will implement management strategies.

The Service will prepare in Environmental Assessment (EA) in accordance with procedures for implementing NEPA found in the Departmental Manual 516 DM 6, Appendix 1.

The Service will contract for a cultural resources overview study in support of the comprehensive conservation plan. The professional study will identify known sites on the refuge. We are also asking the public to

identify any cultural sites that are important to them.

Review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), NEPA Regulations (40 CFR parts 1500-1508), other appropriate Federal laws and regulations, and Service policies and procedures for compliance with those regulations.

We estimate that the draft environmental documents will be available in late 2003.

Dated: November 8, 2002.

**William F. Hartwig,**

*Regional Director.*

[FR Doc. 03-4027 Filed 2-19-03; 8:45 am]

**BILLING CODE 4310-55-M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[WY-060-1320-EL, WYW150210, WYW150318, WYW151134, WYW151643, WYW154001]**

### Notice of Availability of South Powder River Basin Coal Draft Environmental Impact Statement and Federal Coal Notice of Hearing, WY

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Availability (NOA) of a Draft Environmental Impact Statement (DEIS) on four maintenance lease applications received for five Federal coal tracts in the decertified Powder River Federal Coal Production Region, Wyoming, and Notice of public hearing.

**SUMMARY:** Under the National Environmental Policy Act (NEPA) and the implementing regulations, the Bureau of Land Management (BLM) announces the availability of the South Powder River Basin Coal DEIS and announces a public hearing pursuant to 43 Code of Federal Regulations (CFR) 3425.4.

The DEIS analyzes and discloses to the public direct, indirect, and cumulative environmental impacts of issuing five Federal coal leases in the Wyoming portion of the Powder River Basin. The tracts are being considered for sale as a result of the following coal lease applications received from existing mines in the Wyoming Powder River Basin:

- On March 10, 2000, Powder River Coal Company applied for a maintenance coal lease for approximately 4,500 acres (approximately 564 million recoverable tons of coal) in two tracts adjacent to the

North Antelope/Rochelle Mine Complex in Campbell County, Wyoming. The tracts, which are referred to as the NARO North Lease by Application (LBA) Tract and the NARO South LBA Tract, were assigned case numbers WYW150210 and WYW154001, respectively;

- On March 23, 2000, Ark Land Company applied for a maintenance coal lease for approximately 2,799.5 acres (approximately 383.6 million in-place tons of coal) adjacent to the Black Thunder Mine in Campbell County, Wyoming. The tract, which is referred to as the Little Thunder LBA Tract, was assigned case number WYW150318.

- On June 14, 2001, Ark Land Company filed an application to modify the Little Thunder LBA Tract. As currently filed, the tract includes approximately 3449.3 acres and 440 million tons of recoverable coal reserves;

- On July 28, 2000, Triton Coal Company applied for a maintenance coal lease for approximately 1870.6 acres (approximately 173.2 million in-place tons of coal) adjacent to the North Rochelle Mine in Campbell County, Wyoming. The tract, which is referred to as the West Roundup LBA Tract, was assigned case number WYW151134; and,

- On September 12, 2000, Antelope Coal Company applied for a maintenance coal lease for approximately 3,500 acres (approximately 292.5 million in-place tons of coal) adjacent to the Antelope Mine in Campbell and Converse Counties, Wyoming. The tract, which is referred to as the West Antelope LBA Tract, was assigned case number WYW151643.

- On June 27, 2001, Antelope Coal Company filed an application to modify the West Antelope LBA Tract. As currently filed, the tract includes approximately 3,542 acres and 293.9 million tons of in place coal reserves.

The purpose of the public hearing is to solicit comments on the DEIS from the public on the proposed competitive sales of the Federal coal included in the NARO North, NARO South, Little Thunder, West Roundup, and West Antelope LBA tracts, and on the fair market value and maximum economic recovery of the Federal coal included in the five tracts.

**DATES:** Written comments on the DEIS will be accepted for 60 days following the date that EPA publishes their NOA of the DEIS in the **Federal Register**. Requests to be included on the mailing list and to receive copies of the DEIS and notification of the comment period



and hearing date should be sent to the address, facsimile number, or electronic address (address) listed below.

The BLM asks that those submitting comments on the DEIS make them as specific as possible with reference to page numbers and chapters of the document. Comments that contain only opinions or preferences will not receive a formal response; however, they will be considered and included as part of the BLM decision-making process.

Future notification of public meetings, or other public involvement activities, concerning the proposed sales will be provided through public notices, news media releases, or mailings. These notifications will provide at least 15 days notice of public meetings or gatherings and 30 days notice of written comments requests.

**ADDRESSES:** Please address questions, comments, or concerns to the Casper Field Office, Bureau of Land Management, Attn: Nancy Doelger, 2987 Prospector Drive, Casper, Wyoming 82604, fax them to 307-261-7587, or send e-mail comments to the attention of Nancy Doelger at [casper\\_wymail@blm.gov](mailto:casper_wymail@blm.gov). A copy of the DEIS has been sent to affected Federal, State, and local Government agencies; persons, and entities identified as potentially being affected by a decision to lease the Federal coal in these tracts; and persons who indicated to the BLM that they wished to receive a copy of the DEIS. Copies of the DEIS are available for public inspection at the following BLM office locations: Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82009; Bureau of Land Management, Casper Field Office, 2987 Prospector Lane, Casper, Wyoming 82604. Comments, including names and street addresses of respondents, will be available for public review at the address listed above during regular business hours (7:45 a.m. through 4:30 p.m.), Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

**FOR FURTHER INFORMATION CONTACT:** Nancy Doelger or Mike Karbs at the

above address, or telephone: 307-261-7600.

**SUPPLEMENTARY INFORMATION:** The five Federal coal tracts being considered for leasing are adjacent to four mines located south and east of Wright, Wyoming. The operators of these mines applied to lease the tracts as maintenance tracts to extend the life of their existing mining operations under the provisions of the Leasing on Application regulations at 43 CFR 3425. The following paragraphs provide descriptions of the tracts as they were applied for.

On March 13, 2000, Powder River Coal Company filed a coal lease application for the following lands in two tracts adjacent to the North Antelope/Rochelle Mine Complex in Campbell County, Wyoming:

**NARO North—(WYW150210)**

T. 42 N., R. 70 W., 6th PM, Wyoming.  
Sec. 28, lots 5 thru 16;  
Sec. 29, lots 5 thru 16;  
Sec. 30, lots 9 thru 20;  
T. 42 N., R. 71 W., 6th PM, Wyoming.  
Sec. 25, lots 5 thru 15;  
Sec. 26, lots 7 thru 10;  
Sec. 35, lots 1, 2, 7 thru 10, 15, 16.  
Containing 2,369.25 acres, more or less.

**NARO South—WYW 154001**

T. 41 N., R. 70 W., 6th PM, Wyoming.  
Sec. 19, lots 6 thru 11, 12 (S½), 13 thru 20;  
Sec. 20, lots 5 (S½), 6 (S½), 7 (S½), 8 (S½), 9 thru 16;  
Sec. 21, lots 5 (S½), 12, 13;  
Sec. 28, lots 3 thru 6, 11, NE¼ SW¼;  
Sec. 29, lots 1 thru 12;  
Sec. 30, lots 5 thru 12.  
Containing 2,133.635 acres, more or less.

The tracts as applied for include an estimated 564 million tons of recoverable coal. According to the application filed for the NARO North and NARO South LBA Tracts, mining the coal included in these maintenance tracts would extend the life of the North Antelope/Rochelle Mine Complex.

On March 23, 2000, Ark Land Company filed a coal lease application for lands adjacent to the Black Thunder Mine in Campbell County, Wyoming. The following lands are included in the tract as currently filed:

**Little Thunder—WYW150318**

T. 43 N., R. 71 W., 6th PM, Wyoming.  
Sec. 2, lots 5, 6, 11 thru 14, 19, 20;  
Sec. 11, lots 1, 2, 7 thru 10, 15, 16;  
Sec. 12, lots 2 (W½ & SE¼), 3 thru 16;  
Sec. 13, lots 1 thru 16;  
Sec. 14, lots 1, 2, 6 thru 9, 14, 15;  
Sec. 24, lots 1 thru 16;  
Sec. 25, lots 1, 2, 7 thru 10, 15, 16.  
T. 44 N., R. 71 W., 6th PM, Wyoming.  
Sec. 35, lots 1, 2, 7 thru 10, 15, 16. T. 44.  
Containing 3,449.317 acres more or less.

The tract includes an estimated 440 million tons of in-place coal. According to the application, the coal is needed to maintain existing mining operations at the Black Thunder Mine and would be used for electric power generation.

On July 28, 2000, Triton Coal Company, LLC filed a coal lease application for the following lands adjacent to the North Rochelle Mine in Campbell County, Wyoming:

**West Roundup—WYW151134**

T. 42 N., R. 70 W., 6th PM, Wyoming.  
Sec. 6, lots 8-19, 20 (N½), 21 (N½), 22 (N½), 23 (N½);  
Sec. 7, lots 5 (S½), 6 (S½), 7 (S½), 8 (S½), 9 thru 14;  
Sec. 8, lots 1 (SW¼), 2 (S½), 3 (S½), 4 (S½), 5 thru 12;  
Sec. 9, lots 5 (SW¼), 11, 12, 14;  
T. 43 N., R. 70 W., 6th PM, Wyoming.  
Sec. 3, lots 13 thru 20.  
T. 42 N., R. 71 W., 6th PM, Wyoming.  
Sec. 1, lots 5, 6, 11 thru 13.  
Containing 1,870.638 acres more or less.

The tract includes an estimated 173.2 million tons of in-place coal.

On September 12, 2000, Antelope Coal Company filed a coal lease application for lands adjacent to the Antelope Mine in Campbell and Converse Counties, Wyoming. The following lands are included in the tract as currently filed:

**West Antelope—WYW151643**

T. 40 N., R. 71 W., 6th PM, Wyoming.  
Sec. 3, lots 15 thru 18;  
Sec. 4, lots 5 thru 20;  
Sec. 5, lots 5 thru 7, 10 thru 15, 19, 20;  
Sec. 9, lot 1;  
Sec. 10, lots 3, 4;  
T. 41 N., R. 71 W., 6th PM, Wyoming.  
Sec. 28, lots 1 thru 16;  
Sec. 29, lots 1 thru 16;  
Sec. 32, lots 1 thru 3, 6 thru 11, 14 thru 16;  
Sec. 33, lots 1 thru 16.  
Containing 3,542.19 acres more or less.

The West Antelope tract includes an estimated 293.9 million tons of in-place coal. According to the application, mining this coal would extend the life of the existing mine and the coal would be mined for sale to electrical power generating plants. Each of the mines adjacent to the LBA tracts described above (the North Antelope/Rochelle, Black Thunder, North Rochelle, and Antelope mines, respectively) has an approved mining and reclamation plan from the Land Quality Division of the Wyoming Department of Environmental Quality and an approved air quality permit from the Air Quality Division of the Wyoming Department of Environmental Quality. Each of these mines has previously acquired one or more maintenance coal leases using the LBA process.



The DEIS analyzes leasing each of the five tracts (described above) as a separate Proposed Action. As part of the coal leasing process, BLM has identified and is evaluating other tract configurations for these tracts which add or subtract Federal coal to avoid bypassing coal or to increase estimated fair market value of the unleased Federal coal in this area. The tract configurations that BLM has identified for each tract are described and analyzed as alternatives in the DEIS. The DEIS also analyzes the alternative of rejecting each application to lease Federal coal as the No Action Alternative for each tract.

The agency-preferred alternative will vary for each tract, depending on which tract configuration is determined to best advance the public interest in avoiding bypassing Federal coal and obtaining the fair market value of the Federal coal.

The Proposed Actions and Alternatives being considered in the DEIS are in conformance with the "Approved Resource Management Plan for Public Lands Administered by the Bureau of Land Management Buffalo Field Office" (April 2001), the USDA Forest Service "Final EIS for the Northern Great Plains Management Plans Revision" (May 2001) and the BLM "Platte River Resource Area Resource Management Plan" (1985)

The USDA Forest Service (Forest Service) is a cooperating agency in the preparation of the DEIS. The surface of some of the land included for consideration for leasing in three of the tracts (NARO North, Little Thunder, and West Roundup) is National Forest System land administered by the Forest Service as part of the Thunder Basin National Grasslands.

The Office of Surface Mining Reclamation and Enforcement (OSM) is a cooperating agency in the preparation of the DEIS. If the tracts are leased as maintenance tracts, each new lease must be incorporated into the existing mining and reclamation plan for the adjacent mine and the Secretary of the Interior must approve each revision to the MLA (Mineral Leasing Act) mining plan for each mine before the Federal coal in each tract can be mined. OSM is the Federal agency that would be responsible for recommending approval, approval with conditions, or disapproval of the revised MLA mining plans to the office of the Secretary of the Interior if any or all of these tracts are leased.

Dated: December 10, 2002.

**Alan L. Kesterke,**

*Acting State Director.*

[FR Doc. 03-4177 Filed 2-19-03; 8:45 am]

**BILLING CODE 4310-22-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[CA-310-1820-AE]**

#### Notice of Public Meeting: Northwest California Resource Advisory Council

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA), the U. S. Department of the Interior, Bureau of Land Management (BLM) Northwest California Resource Advisory Council will meet as indicated below.

**DATES:** The meeting will be held Wednesday and Thursday, April 2 and 3, 2003, at Granzella's Inn, 391 Sixth St., Williams, Calif. On April 2, the meeting convenes at 10 a.m. for a field trip to public lands managed by the BLM Ukiah Field Office. Members of the public are welcome. They must provide their own transportation and lunch. On April 3, the meeting begins at 8 a.m. in the Conference Room at Granzella's. Time for public comments has been set aside for 1 p.m. on April 3.

**FOR FURTHER INFORMATION CONTACT:** Rich Burns, BLM Ukiah field manager, 2550 North State St., Ukiah, CA, (707) 468-4000; or BLM Public Affairs Officer Joseph J. Fontana, telephone (530) 252-5332.

**SUPPLEMENTARY INFORMATION:** The 12-member council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Northwest California. At this meeting, agenda topics will include council comments on proposed changes to BLM's grazing regulations, proposals for wind energy development, and discussion about the voting protocol established in the RAC charter. The council will also hear status reports from the managers of the BLM's Arcata, Ukiah and Redding field offices.

All meetings are open to the public. Members of the public may present written comments to the council. Each formal council meeting will have time allocated for public comments. Depending on the number of persons

wishing to speak, and the time available, the time for individual comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation and other reasonable accommodations, should contact the BLM as provided above.

Dated: February 13, 2003.

**Joseph J. Fontana,**

*Public Affairs Officer.*

[FR Doc. 03-4033 Filed 2-19-03; 8:45 am]

**BILLING CODE 4310-40-P**

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### Outer Continental Shelf (OCS), Beaufort Sea Oil and Gas Lease Sale 186

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Availability of the Proposed Notice of Sale.

**SUMMARY:** Alaska OCS, Beaufort Sea; Notice of Availability of the proposed Notice of Sale for proposed Oil and Gas Lease Sale 186 in the Beaufort Sea. This Notice is published pursuant to 30 CFR 256.29(c) as a matter of information to the public.

With regard to oil and gas leasing on the OCS, the Secretary of the Interior, pursuant to section 19 of the OCS Lands Act, provides the affected States the opportunity to review the proposed Notice. The proposed Notice sets forth the proposed terms and conditions of the sale, including minimum bids, royalty rates, and rentals.

The proposed Notice of Sale for Sale 186 and a "Proposed Sale Notice Package" containing information essential to potential bidders may be obtained from the Alaska OCS Region, Information Resource Center, Minerals Management Service, 949 East 36th Avenue, Room 330, Anchorage, Alaska 99508-4302. Telephone: (907) 271-6070 or 1-800-764-2627. Certain documents may be viewed and downloaded from the MMS World Wide Web site at <http://www.mms.gov/alaska>.

The final Notice of Sale will be published in the **Federal Register** at least 30 days prior to the date of bid opening. Bid opening is currently scheduled for September 24, 2003.

Dated: February 11, 2003.

**Walter D. Cruickshank,**

*Acting Director, Minerals Management Service.*

[FR Doc. 03-4051 Filed 2-19-03; 8:45 am]

**BILLING CODE 4310-MR-P**

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****Importation of Controlled Substances; Notice of Application**

Pursuant to Section 1008 of the Controlled Substances Import and Export Act 921 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a registration under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Section 1301.34 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on May 13, 2002, Chatterm Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration to be registered as an importer of phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import the listed controlled substance to bulk manufacture controlled substances.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than March 24, 2003.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements

for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: February 5, 2003.

**Laurel M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 03-4097 Filed 2-19-03; 8:45 am]

**BILLING CODE 4410-09-M**

**DEPARTMENT OF JUSTICE****Immigration and Naturalization Service****Agency Information Collection Activities: Proposed Collection; Comment Request**

**ACTION:** 30-Day Notice of Information Collection under Review: Aircraft/Vessel Report, Form I-92

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on November 21, 2002 at 67 FR 70243, allowing for a 60-day public review and comment period on the extension of the proposed information collection. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 24, 2003. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725-17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Overview of this information collection:*

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Aircraft/Vessel Report.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I-92, Inspections Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is part of the manifest requirements of Section 231 and 251 of the Immigration and Nationality Act and is used by the Immigration and Naturalization Service and other agencies for data collection and statistical analysis.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 720,000 responses at 11 minutes (.183 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 129,600 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202-514-3291, Director, Regulations and Forms Services Division, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of

Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: February 14, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.*

[FR Doc. 03-4091 Filed 2-19-03; 8:45 am]

**BILLING CODE 4410-10-M**

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**ACTION:** 30-day notice of information collection under review: passenger list, crew list; Form I-418.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on November 21, 2002 at 67 FR 70243, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 24, 2003. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725-17th Street, NW., Room 10235, Washington, DC 20530.

Written comment and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Passenger List, Crew List.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I-418, Inspections Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is prescribed by the Attorney General for the INS for use by masters, owners or agents of vessels in complying with sections 231 and 251 of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 95,000 responses at 1 hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 95,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202-514-3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: February 14, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, Department of Justice, Immigration and Naturalization Service.*

[FR Doc. 03-4092 Filed 2-19-03; 8:45 am]

**BILLING CODE 4410-10-M**

## DEPARTMENT OF JUSTICE

### National Institute of Corrections

#### Solicitation for a Cooperative Agreement—"Executive Training for Women—Team Development"

**AGENCY:** National Institute of Corrections, Department of Justice.

**ACTION:** Solicitation for a Cooperative Agreement.

**SUMMARY:** The Department of Justice (DOJ), National Institute of Corrections (NIC), announces the availability of funds in FY 2003 for a cooperative agreement to fund the project, "Executive Training for Women—Team Building". NIC invites applications for a one year cooperative agreement to design and deliver a three-day team development training program. Participants will be selected graduates of the two prior Executive Leadership Training for Women programs and the participant's chosen senior administrator. The participant has determined that this administrator is critical to her success in her current position, and is supportive of her efforts to succeed and grow in the organization.

This third program offering continues the leadership development of the woman executive by inviting other key personnel into the process to work together as a highly productive and respectful team. This particular team approach should incorporate researched and documented leadership styles of both men and women. The award recipient must become familiar with Phase 1 and Phase 2 of the NIC Executive Leadership Training for Women Program in order to understand the program history and progression to this advanced level of training, designed for selected graduates of the Phase 1 and 2 program. The cooperative agreement includes the responsibility for the program and curriculum design, training of faculty, and the delivery and evaluation of the pilot program in FY 2004. A total of \$100,000 is reserved for the project during fiscal year 2003.

This cooperative agreement is a form of assistance relationship where the National Institute of Corrections is substantially involved during the performance of the award. The recipient

of the award will be selected through the competitive solicitation process.

**DATES:** Applications must be received by 4:00 p.m. Eastern Standard Time on April 15, 2003.

**ADDRESSES:** Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street, NW., Room 5007, Washington, DC 20534.

Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date as mail at NIC is still being delayed due to recent events.

Hand delivered applications should be brought to 500 First Street, NW., Washington, DC 20534. At the front desk, call (202) 307-3106 extension 0 for pickup. Faxed or e-mailed applications will not be accepted.

**FOR FURTHER INFORMATION CONTACT:** A copy of this announcement and the required application forms can be downloaded from the NIC Web page at <http://www.ncic.org> (click on "Cooperative Agreements"). Hard copies of the application can be obtained by calling Rita Rippetoe, (800) 995-6423, extension 44222 or by e-mail [rrippetoe@bop.gov](mailto:rrippetoe@bop.gov).

All technical and or programmatic questions concerning this announcement should be directed to Evelyn Bush at the above address or by calling (800) 995-6423, extension 40376 or (202) 514-0376 or by e-mail via [elbush@bop.gov](mailto:elbush@bop.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The National Institute of Corrections, Prisons Division, offered the first Executive Training for Women program in 1994. The program was designed to address both the personal and professional aspects of correctional leadership and has continued to build upon the success of that beginning effort. Through a three part series focusing on executive, strategic and organizational leadership, NIC has sought to "close the gap" for women executives in their knowledge, self and observer perception, and recognition of their value to the organization. the ultimate goal of the program is to assist the leader with the final integration of her professional awareness and its value to the agency "team" in problem-solving and policy planning.

Developed in 1993, the first program was conducted in 1994. The program concept dates back to the late 1980's and early 1990's, as the National Institute of Corrections recognized the continued under-representation of women executives in corrections throughout the country. While women

have made significant achievements in correctional employment over the last few decades, promotion to the Executive level has been slow. At no time in the history of state departments of corrections in the United States have women held even 20% of all of the Department Director positions. While the entry door into the corrections field swings open wider, it is less so for the promotional door toward advancement. Since entry can no longer be legally prohibited. There are more and more women employed in the field, expecting to be regarded with professional equality and upward mobility opportunities.

NIC's response to the dilemma of women being under-represented in executive level positions in the field of corrections was to establish an Executive Leadership Training for Women Program. With the addition of this third phase, the program is designed to enhance the ability of women to achieve and to function effectively in executive-level positions in state departments of corrections. Phase 1 and 2 have recently (2002) been updated to include the latest research on leadership theories and women's leadership.

##### *Phase 1: Executive Leadership*

A five-day program focused on leadership development. A number of assessments are combined with experiential activities and simulations to focus behavior (self-mastery), leadership competency, clarify current and future personal and professional goals, and accelerate promotional achievement.

##### *Phase 2: Strategic Leadership*

This three-day follow up program was developed in 1995 based on needs assessments from Phase 1 participants. As an expansion of the first program, key elements included strategic competency, the leader's role in the organization, and the moving the organization forward.

##### *Phase 3: Team Building*

The outcome of this cooperative agreement will be a three-day (24 hour) pilot program to build organizational competency by focusing on the group dynamics of the organization and the relationships necessary to succeed. Special attention should be given to the use of innovative problem-solving, and the role of "executive teaming" with recognition of the unique strengths and weaknesses of each team member.

##### **Program Outcomes**

Expand agency leadership capacity by addressing partnerships and relationship skills necessary to create a climate for understanding, growth and support of its key personnel;

Incorporate strategies for the organization's success (mission) by the promotion of effective leadership communication for problem solving discussions and policy planning;

Overcoming barriers to team performance by recognition of individual attributes and talents;

Create an atmosphere that encourages "coaching" as an agency benefit.

*Purpose:* The National Institute of Corrections is seeking applications for a cooperative agreement that will design and deliver a 3-day interactive pilot program, focused on agency team development. The program design must provide the opportunity for the executives to comfortably and effectively work to approach problems and policy planning. Recognizing and valuing the woman's leadership style, the emphasis of this third training program is to successfully integrate the individual styles into creative teams. This is accomplished by bringing the woman leader to the training program together with the next upper-level supervisor that is most supportive of her career efforts and her organizational value. The pilot program will be modified, if necessary, based on the participant and faculty evaluation.

##### **Scope of Work**

1. Design and implement a program based on current leadership and gender research which identifies the competencies necessary for a group of people to work as a highly productive and cohesive team. Expected components include, but are not limited to: Communicating Effectively in Teams, Problem Solving & Resolving Team Conflicts, Interrelationship Dynamics and Consensus Building.

2. Awardee must become acquainted with the current Executive Leadership Training for Women Program (Phase 1 and Phase 2) via written materials, participant manual and discussion with the current contractor. Additionally, attendance by one team member is required at the September 2003 Executive program in Maryland.

3. Identify in the proposal specific strategies for assuring a collaborative effort between their project team and NIC. This will include the curriculum review and pre-approval, program planning session, manual materials, and the selection and training of faculty for the program.

4. Conduct a program planning session, prepare program agenda, participant manual, and train staff/faculty for program delivery. All associated overhead slides, presentations, participant manual and any other audio-visual materials, with copyright permission, are to be provided to NIC. (Use CD-Rom.)

5. "Pilot" the Executive Training for Women-Team Development program in FY04 to an audience of 24 to 30 correctional practitioners;

6. Develop an evaluation tool, disseminate to participants and compile a basic analysis of the program, with results to the NIC Project Monitor within 30 days of the 2004 program completion.

7. Applicants are encouraged to include one or more graduates of the NIC Executive Leadership Training Program for Women in their project, i.e. planning meeting, project team. Specific names are not required, but positions must be identified in the budget with respective faculty roles identified.

#### Specific Requirements

1. Based on research of the existing leadership theories and realizing that those who had studied women executives discovered that the learning process needed to be complimented by a supportive environment. Applicants should consider "The Setting" as well as the style and methods of the program presentation. The location for the training will be recommended by the awardee with the final decision remaining with NIC.

The setting and learning environment incorporated in, and critical to, leadership training suggests the following consideration when attempting to locate a suitable site:

A. private outdoor space, preferably a grassed area to accommodate two groups of ten (10) to twelve (12) to execute team building activities;

B. secluded indoor and outdoor space conducive to individual and team problem solving, and personal reflection time;

C. classroom space that will accommodate 30 adults plus podium, LCD set-up, display table, and refreshment table;

D. dining area (separate from the public and classroom area) that will accommodate up to 30 people,

2. The applicant must demonstrate that the project team is comprised of at least one person with expertise in women's leadership education; one with expertise in executive team building and at least one with correctional administration/management experience at no less than the Warden/

Superintendent level. This experience should be clearly identified in the accompanying resumes. Each individual must submit signed letters stating their willingness to work on this project.

3. The person designated as project director is required to be the person who will be on-site and coordinate the 3-day program presentation and who has full decision-making authority to work with the NIC project manager. This person must have experience at the level of a Warden and have enough time dedicated to the project to assure availability for detailed collaboration with the NIC project manager.

4. Participants for the pilot program will be sought from women leaders who have participated in the two previous offerings, advising them of a special opportunity to explore additional leadership training, accompanied by a supportive, senior administrator. Since the size of the program will be limited, the applicant for this cooperative agreement is being asked to propose creative and relevant criteria for the admission of the Executive Woman (+1) to the Phase 3 training.

5. The applicant should provide a clear design of what the 3 day program will look like including, but not limited to, a sessions by topic and time frames, activities/exercises by type and learning objective, and debriefing/processing time frames.

6. Interactive activities should be targeted to increased learning and understanding of team dynamics, strengths, etc. No activities should require a level of physical fitness greater than an average 50 year old person could perform. The majority of the activities should assure that the executive women and the senior administrator from the state interact during the course of the exercises.

7. All proposed interactive team activities should have a specific learning objective. The technique for processing the exercise or activity to achieve the learning objective should be clearly explained.

8. The applicant is to include a variety of interactive team activities, which, after concluding, will be thoroughly debriefed to achieve the learning objective. Although there is no prohibition from using outdoor, physical activities, such team activities are not to predominate.

9. The awardee must follow all of NIC's procedures and time frames for the provision of training and this must be stated in the proposal;

10. Dates for the training program will be determined by NIC in consultation with the awardee;

11. NIC will receive applications and select participants for the program.

12. Applicants should identify in the proposal specific strategies for assuring a collaborative effort between the project team and the NIC project manager. This will include the planning session, manual materials, and the selection of faculty for the program.

#### Application Requirements:

Applications must be submitted using OMB Standard Form 424, Federal Assistance and attachments. Copies can be downloaded from the NIC Web page at <http://www.nicic.org/services/coop/default.htm>. The applications should be concisely written, typed double spaced and refer to the project by the "NIC Application Number" and Title in this announcement.

Submit an original and two copies. The original should have the applicant's signature in blue ink. A cover letter must identify the responsible audit agency for the applicant's financial accounts. The narrative portion of this cooperative agreement application should include, at a minimum:

1. A brief paragraph indicating the applicant's understanding of the purpose of this cooperative agreement;

2. One or more paragraphs detailing the applicants understanding of women leadership;

3. A brief paragraph that summarizes the project goals and objectives;

4. A clear description of the methodology that will be used to complete the project and achieve its goals;

5. A clearly developed Project Plan which demonstrates how the various goals and objectives of the project will be achieved through its various activities to produce the required results;

6. Chart of measurable project milestones and time lines for the completion of each milestone;

7. A description of the qualifications of the applicant organization and each project staff;

8. A description of the staffing plan for the project, including the role of each project staff, the time commitment for each, the relationship among the staff (who reports to whom), and a statement from individual staff that they will be available to work on this project;

9. A budget detailing all costs for the project, shows consideration for all contingencies for this project, and notes a commitment to work within the budget proposed (budget should be divided into object class categories as shown on application Standard Form 424A). A budget narrative must be included which explains how all costs were determined.

**Authority:** Public Law 93-415.

**Funds Available:** The award will be limited to a maximum of \$100,000 (direct and indirect costs). Participant travel will be arranged for and paid by NIC. All other costs must be outlined in the proposal's budget. Funds may only be used for the activities that are linked to the desired outcome of the project. No funds are transferred to state or local governments. Based upon satisfactory performance of the awardee and the availability of funding in future years, a supplemental award could be made available for continued program delivery.

This project will be a collaborative venture with the NIC Prisons Division.

### Antideficiency Act

Nothing contained herein shall be construed to obligate the parties to any expenditure or obligation of funds in excess or in advance of appropriation in accordance with the Antideficiency Act, 31 U.S.C. 1341

**Eligibility of Applicants:** An eligible applicant is any state or general unit of local government, private agency, educational institution, organization, individuals or team with expertise in the requested areas.

**Review Considerations:** Applications received under this announcement will be subjected to a 3 to 5 member Peer Review Process.

**Number of Awards:** One (1).

**NIC Application Number:** 03P22. This number should appear as a reference line in the cover letter and also in box 11 of Standard Form 424 and on the outside of the envelope in which the application is sent.

**Catalog of Federal Domestic Assistance Number is:** 16.601, Title: Training and Staff Development.

**Executive Order 12362:** This program is not subject to the provisions of Executive Order 12372.

Dated: February 12, 2003.

**Morris L. Thigpen,**

*Director, National Institute of Correction.*

[FR Doc. 03-4023 Filed 2-19-03; 8:45 am]

**BILLING CODE 4410-36-M**

## DEPARTMENT OF JUSTICE

### National Institute of Corrections

#### Solicitation for a Cooperative Agreement—"Operational Practices for Women Offenders"

**AGENCY:** National Institute of Corrections, Department of Justice.

**ACTION:** Solicitation for a Cooperative Agreement.

**SUMMARY:** The Department of Justice (DOJ), National Institute of Corrections (NIC), announces the availability of funds in FY 2003 for a cooperative agreement to fund the project "Operational Practices for Women Offenders." NIC will award a two year cooperative agreement to review the current training program, develop a curriculum, prepare an accompanying participant and trainer manual and attend the May 2003 program for insight into the current components. In addition, the award recipient will be responsible for the final (NIC approved) curriculum, training of faculty for the program and the delivery of the program in FY 2004, with the participant and trainer manuals in place. A total of \$120,00 is reserved for the project during fiscal years 2003 and 2004. The 2003 allocation is \$20,000 and the 2004 allocation is \$100,000.

A cooperative agreement is a form of assistance relationship where the National Institute of Corrections is substantially involved during the performance of the award. The recipient of the award will be selected through the competitive solicitation process.

**DATES:** Applications must be received by 4 p.m. Eastern Standard Time on March 27, 2003.

**ADDRESSES:** Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street, NW., Room 5007, Washington, DC 20534. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date as mail at NIC is still being delayed due to recent events.

Hands delivered applicants should be brought to 500 First Street, NW., Washington, DC 20534. At the front desk, call (202) 307-3106, extension 0 for pickup. Faxed or emailed applications will not be accepted.

**FOR FURTHER INFORMATION CONTACT:** A copy of this announcement and the required application forms can be downloaded from the NIC web page at [www.nicic.org](http://www.nicic.org) (Click on "cooperative agreements.") Hard copies of the announcement can be obtained by calling Rita Rippetoe at 1-800-995-6423 extension 44222 or e-mail [rippetoe@bop.gov](mailto:rippetoe@bop.gov).

All technical or programmatic questions concerning this announcement should be directed to Evelyn Bush, Correctional Program Specialist, National Institute of Corrections. She can be reached by calling 1-800-995-6423 extension 40376 or by e-mail at [elbush@bop.gov](mailto:elbush@bop.gov). Supplemental information regarding the program can be received by mail or e-

mail. Please contact Sharon Floyd at 1-800-995-6423 ext 44072.

### SUPPLEMENTARY INFORMATION:

**Background:** The National Institute of Corrections, Prisons Division, began its work defining critical issues that impact women offenders in 1996. Based on surveys, workshops and state-driven inquiries for assistance and information, NIC began addressing gender-specific needs and services.

The program goal is to provide assistance to state departments of correction around the specific issues and concerns dealing with women offenders.

The "Operational Practices for Women Offenders" program was developed with the practitioner in mind, to help correctional managers increase their understanding of women offenders and enhance their skills for effectively working with them.

The role of the correctional institution has changed a great deal over the past 200 years. The almshouses and dungeons of the early days gave way to custodial institutions and then to reformatories. Today, correctional facilities are making new strides in providing improved conditions, diversity and quality in programming, and availability of educational, vocational, treatment and medical services.

Both theorists and popular viewpoint have played a role in the structure of corrections for the women offender. The current trend is to dispel traditional stereotypes and myths surrounding the woman offender, to develop a realistic picture of the variety of women in the penal system today, and to address the individual and group needs of these women.

As a number of women entering the Criminal Justice system grew, (at a faster rate than men) practitioners felt the impact based on the growing number of operational issues. These included concerns about searches, contraband, privacy, etc. NIC became involved in responding to these requests for assistance to "do it the right way and the appropriate way."

Differences in women's pathways into the criminal justice system and women's behavior while in custody have important implications for the practices in women's prisons. There is significant evidence that the response of women to incarceration, treatment, and rehabilitation differs from that of men.

Gender responsiveness has been defined by Bloom and Covington as "creating an environment that reflects an understanding of the reality of women's lives and addresses the issues

of women.” As the criminal justice system becomes more responsive to the issues of managing women offenders, it will be more effective in targeting the pathways to offending that propel women into, and return them to, the criminal justice system.

Taken from Gender Responsive Strategies: Research, Practice and Guiding Principles for Women Offenders, NIC 2002)

**Purpose:** The National Institute of Corrections is seeking applications for a cooperative agreement that will take over management of an existing program, develop and produce a curriculum with a corresponding participant and trainer’s manual. In addition, the awardee will deliver subsequent offerings of the 5 day interactive program. The product should be “user-friendly” so that will be effective and useful to state departments of corrections. The pilot program will be modified, if necessary, based on the final program review and evaluation.

**Scope of Work:** 1. Review the current NIC training program; design a curriculum that incorporates the most up-to-date research on women offenders with the objective to prepare correctional managers to work effectively with women offenders; describe the methodology for identifying any recommended or significant change.

2. Produce a program curriculum, participant manual and trainer’s guide that is user-friendly and designed for interactive, adult learning. All overheads slides, presentations and other audio-visual materials, with copyright permission, are to be included.

3. Conduct a program planning session and train staff/trainers for program delivery;

4. “Pilot” “Operational Practices for Women Offenders” training program in May 2004 to an audience of 25 to 30 correctional practitioners;

5. Develop, disseminate, and compile results of participant program evaluation, with results to the NIC Project Monitor, within 30 days of the May 2004 program completion.

6. Design and pilot test an impact evaluation instrument to be completed by participants 9–12 months after attending the training.

**Specific Requirements:** 1. Significant changes to the existing curriculum must be justified with research-based documentation.

2. Attendance of at least one primary team member is required for the duration of the May 2003 program. There must be included in the proposal a statement that this primary team

member will attend the training program May 19–23, 2003, with the costs reflected in the budget narrative.

3. The applicant must demonstrate that the project team is comprised of persons with expertise in correctional administration/management with women offenders as well as project staff who specifically have experience in correctional management and gender-specific responsive programming.

4. All identified trainers for the training program must have recent (within five years) experience in working with women offenders, as either staff or consultant. This experiences should be clearly identified in the resume or narrative.

5. The person designated as project director is required to be the person who will manage the 5 day on-site program presentation (2004) and who has full decision-making authority to work with the NIC project manager. This person must have sufficient time dedicated to the project to assure availability for collaboration with the NIC project manager.

6. Applicants should identify in the proposal specific strategies for assuring a collaborative effort between their project team and NIC. This will include the planning session, manual materials, and the selection of trainers for the program. The applicant should demonstrate ability to work collaboratively with NIC from previous work, if applicable.

7. The awardee must follow all of NIC’s procedures and time frames for the provision of training and this must be stated in the proposal. Dates for the training program will be determined by NIC in consultation with the awardee.

8. Location for the training program will be recommended by the awardee but the final decision for a site will remain with NIC.

**Application Requirements:** Applications must be submitted using OMB Standard Form 424, Federal Assistance, and attachments. (Copies can be downloaded from the NIC web page at [www.nicic.org/service/coop/default.htm](http://www.nicic.org/service/coop/default.htm).) The applications should be concisely written, typed double-spaced and refer to the project by the “NIC Application Number” and Title is this announcement.

Submit an original and two copies. The original should have the applicant’s signature in blue ink. A cover letter must identify the responsible audit agency for the applicant’s financial accounts.

The narrative portion of this cooperative agreement application should include, at a minimum:

1. A brief paragraph indicating the applicant’s understanding of this cooperative agreement;

2. One or more paragraphs detailing the applicants understanding of the historical and current views of working with women offenders, and the response for effectively working with women offenders;

3. A brief paragraph summarizing the project goals and objectives;

4. A clear description of the methodology for project completion and achievement of its goals;

5. A clearly developed Project Plan which demonstrates how and when the various goals and objectives of the project will be achieved through its various activities so as to produce the required results;

6. A chart of measurable project milestones and time lines for the completion of each milestone;

7. A description of the qualifications of the applicant organization and each project staff;

8. A description of the staffing plan for the project, including the role of each project staff, the percentage of the time commitment for each (in days), the relationship among the staff (who reports to whom), and a statement from individual staff that they will be available to work on this project and meet the required level of experience.

9. A budget detailing all costs for the project, costs for trainer services and travel, shows consideration for all contingencies for this project, and notes a commitment to work within the budget proposed. Budget should be divided into object class categories as shown on application Standard Form 424A. A budget narrative must be included which explains how all costs were determined.

**Authority:** Public Law 93–415.

**Funds Available:** The award will be limited to a maximum of \$120,000 (direct and indirect costs). Participant travel for the program delivery will be paid by NIC and is not included in the funding for this project. Funds may only be used for the activities that are linked to the desired outcome of the project. No funds are transferred to State or local governments. This project will be a collaborative venture with the NIC Prisons Division. NIC retains the right to select the applicants for participation. \$20,000 will be allocated for fiscal year 2003, and \$100,000 will be allocated for fiscal year 2004.

#### **Antideficiency Act**

Nothing contained herein shall be construed to obligate the parties to any expenditure or obligation of funds in



excess or in advance of appropriation in accordance with the Antideficiency Act, 31 U.S.C. 1341.

**Eligibility Applicants:** An eligible applicant is any State or general unit of local government, private agency, educational institution, organization, individuals or team with expertise in the requested areas in order to successfully meet the objectives of this project.

**Review Considerations:** Applications received under this announcement will be subjected to a 3- to 5-member Peer Review Process.

**Number of Awards:** One (1).

**NIC Application Number:** 03P21. This number should appear as a reference line in the cover letter and also in box 11 of Standard Form 424, and on the outside of the envelope in which the application is sent.

**Executive Order 12372:** This program is not subject to the provisions of Executive Order 12372.

(Catalog of Federal Domestic Assistance Number is: 16.601, Title: Training and Staff Development).

Dated: February 12, 2003.

**Morris L. Thigpen,**

*Director, National Institute of Corrections.*

[FR Doc. 03-4022 Filed 2-19-03; 8:45 am]

**BILLING CODE 4410-36-M**

## NATIONAL INSTITUTE FOR LITERACY

### Notice of Meeting

**AGENCY:** National Institute for Literacy (NIFL).

**SUMMARY:** This notice sets forth the schedule and proposed agenda of a

forthcoming meeting of the National Institute for Literacy Board (Advisory Board). This notice also describes the function of the Advisory Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend the meeting.

**DATE AND TIME:** March 4, 2003 from 9:30 a.m. to 4:30 p.m. and March 5, 2003 from 9:30 a.m. to 1 p.m.

**ADDRESSES:** National Institute for Literacy, 1775 I Street, NW., Suite 730, Washington, DC 20006.

**FOR FURTHER INFORMATION CONTACT:** Liz Hollis, Special Assistant to the Director, National Institute for Literacy, 1775 I Street, NW., Suite 730, Washington, DC 20006. Telephone number (202) 233-2072, e-mail: [ehollis@nifl.gov](mailto:ehollis@nifl.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Board is established under the Workforce Investment Act of 1998, Title II of Pub. L. 105-220, Sec. 242, the National Institute for Literacy. The Advisory Board consists of ten individuals appointed by the President with the advice and consent of the Senate. The Advisory Board is established to advise and make recommendations to the Interagency Group, composed of the Secretaries of Education, Labor, and Health and Human Services, which administers the National Institute for Literacy (Institute). The Interagency Group considers the Advisory Board's recommendations in planning the goals of the Institute and in the implementation of any programs to achieve the goals of the Institute. Specifically, the Advisory Board

performs the following functions: (a) Makes recommendations concerning the appointment of the Director and the staff of the Institute; (b) provides independent advice on operation of the Institute; and (c) receives reports from the Interagency Group and Director of the Institute. In addition, the Institute consults with the Advisory Board on the award of fellowships. The National Institute for Literacy Advisory Board meeting on March 4-5, 2003, will focus on future and current NIFL program activities, the upcoming reauthorization of the Workforce Investment Act, and other relevant literacy activities and issues. Records are kept of all Advisory Board proceedings and are available for public inspection at the National Institute for Literacy, 1775 I Street, NW, Suite 730, Washington, DC 20006, from 8:30 a.m. to 5 p.m.

Dated: February 14, 2003.

**Sandra L. Baxter,**

*Interim Executive Director.*

[FR Doc. 03-4141 Filed 2-19-03; 8:45 am]

**BILLING CODE 6055-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Submission for OMB Review; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

*Extension:*

Form N-54A .....	SEC File No. 270-182 .....	OMB Control No. 3235-0237
Form N-54C .....	SEC File No. 270-184 .....	OMB Control No. 3235-0236
Form N-6F .....	SEC File No. 270-185 .....	OMB Control No. 3235-0238

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (the "Act"), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the previously approved collections of information discussed below.

• *Form N-54A under the Investment Company Act of 1940; Notification of Election to be Subject to Sections 55 through 65 of the Investment Company Act of 1940 Filed Pursuant to Section 54(a) of the Act*

Form N-54A (17 CFR 274.53) is the notification of election to the Commission to be regulated as a

business development company. A company making such an election only has to file a Form N-54A once.

It is estimated that approximately 4 respondents per year file with the Commission a Form N-54A. Form N-54A requires approximately 0.5 burden hours per response resulting from creating and filing the information required by the Form. The total burden hours for Form N-54A would be 2.0 hours per year in the aggregate. The estimated annual burden of 2.0 hours represents an increase of 1.0 hour over the prior estimate of 1.0 hour. The increase in burden hours is attributable to an increase in the number of respondents from 3 to 4.

• *Form N-54C under the Investment Company Act of 1940, Notification of Withdrawal of Election to be Subject to Sections 55 through 65 of the Investment Company Act of 1940 Filed Pursuant to Section 54(c) of the Investment Company Act of 1940*

Form N-54C (17 CFR 274.54) is a notification to the Commission that a company withdraws its election to be regulated as a business development company. Such a company only has to file a Form N-54C once.

It is estimated that approximately 8 respondents per year file with the Commission a Form N-54C. Form N-54C requires approximately 1 burden hour per response resulting from



creating and filing the information required by the Form. The total burden hours for Form N-54C would be 8 hours per year in the aggregate. The estimated annual burden of 8 hours represents a decrease of 4 hours over the prior estimate of 12 hours. The decrease in burden hours is attributable to a decrease in the number of respondents from 12 to 8.

• *Form N-6F under the Investment Company Act of 1940, Notice of Intent to Elect to be Subject to Sections 55 through 65 of the Investment Company Act of 1940*

Certain companies may have to make a filing with the Commission before they are ready to elect on Form N-54A to be regulated as a business development company.<sup>1</sup> A company that is excluded from the definition of "investment company" by section 3(c)(1) of the Investment Company Act of 1940 because it has fewer than one hundred shareholders and is not making a public offering of its securities may lose such an exclusion solely because it proposes to make a public offering of securities as a business development company. Such a company, under certain conditions, would not lose its exclusion if it notifies the Commission on Form N-6F [17 CFR 274.15] of its intent to make an election to be regulated as a business development company. The company only has to file a Form N-6F once.

It is estimated that approximately 0 respondents per year file with the Commission a Form N-6F. Form N-6F requires approximately 0.5 burden hours per response resulting from creating and filing the information required by the Form. The total burden hours for Form N-6F would be 0 hours per year in the aggregate but we are requesting one hour for administrative purposes. The estimated annual burden of 1.0 hour represents no change from the prior estimate of 1.0 hour.

The estimates of average burden hours for Forms N-54A, N-54C and N-6F are made solely for the purposes of the Act and are not derived from a comprehensive or even representative survey or study of the cost of Commission rules and forms.

The collections of information under Forms N-54A, N-54C and N-6F are mandatory. The information provided by such Forms is not kept confidential. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless it displays a currently valid OMB control number.

General comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503; and (ii) Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: February 11, 2003.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03-4043 Filed 2-19-03; 8:45 am]

**BILLING CODE 8010-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47363; File No. SR-CTA/CQ-2002-01]

### Consolidated Tape Association; Order Approving the Fourth Substantive Amendment to the Second Restatement of the Consolidated Tape Association Plan and the Second Substantive Amendment to the Restated Consolidated Quotation Plan

February 12, 2003.

#### I. Introduction

On December 16, 2002, the Consolidated Tape Association ("CTA") Plan and Consolidated Quotation ("CQ") Plan Participants ("Participants")<sup>1</sup> submitted to the Securities and Exchange Commission ("SEC" or "Commission") a proposal to amend the CTA and CQ Plans (collectively, the "Plans"), pursuant to Rule 11Aa3-2<sup>2</sup> under the Securities Exchange Act of 1934 ("Act"). The proposal represents the 4th substantive amendment made to the Second Restatement of the CTA Plan ("4th Amendment") and the 2nd substantive amendment to the Restated CQ Plan ("2nd Amendment"), and reflects

<sup>1</sup> Each Participant executed the proposed amendments. The Participants are the American Stock Exchange LLC ("AMEX"); Boston Stock Exchange, Inc. ("BSE"); Chicago Board Options Exchange, Inc. ("CBOE"); Chicago Stock Exchange, Inc. ("CHX"); Cincinnati Stock Exchange, Inc. ("CSE"); National Association of Securities Dealers, Inc. ("NASD"); New York Stock Exchange, Inc. ("NYSE"); Pacific Exchange, Inc. ("PCX"); and Philadelphia Stock Exchange, Inc. ("PHLX").

<sup>2</sup> 17 CFR 240.11Aa3-2.

several changes unanimously adopted by the Participants. The proposed amendments would introduce a capacity planning process into the Plans and would allocate among the Participants the costs associated with their capacity needs under the Plans. Notice of the proposed amendments was published in the **Federal Register** on December 26, 2002.<sup>3</sup>

Through the Notice, and pursuant to Rule 11Aa3-2(c)(4) under the Act,<sup>4</sup> the Commission granted temporary summary effectiveness to the 4th Amendment to the CTA Plan and the 2nd Amendment to the CQ Plan. The Commission received no comments on the proposed amendments. The summary effectiveness expires on June 26, 2002.<sup>5</sup> This order approves the 4th Amendment to the CTA Plan and the 2nd Amendment to the CQ Plan on a permanent basis.

#### II. Description of the Proposed Amendments

Through the proposed amendments to the Plans, the Participants have introduced a new capacity planning process into the Plans. The Participants will engage in the capacity planning process on a semi-annual basis. The proposed capacity planning process requires each Participant to submit its projected capacity needs directly to the Securities Industry Automation Corporation ("SIAC" or "Processor"), the processor under both Plans. The process avoids any need for Participants to share their individual capacity needs with one another. SIAC will provide each Participant with aggregate capacity projections for all Participants, but will not provide any individual Participant's capacity projections with any other Participant.

Under the proposed plan:

##### *Semi-Annual Planning Cycles:*

1. At the start of each semi-annual capacity planning cycle, each Participant will develop and submit to SIAC an initial set of projected capacity needs.

2. Once it receives all of the initial sets of projected capacity needs, SIAC will aggregate the initial projected capacity requirements for all of the Participants and will notify each Participant as to:

<sup>3</sup> Securities Exchange Act Release No. 47030 (December 18, 2002), 67 FR 78832 ("Notice").

<sup>4</sup> 17 CFR 240.11Aa3-2(c)(4).

<sup>5</sup> Pursuant to Rule 11Aa3-2(c)(4) under the Act, 17 CFR 240.11Aa3-2(c)(4), summary effectiveness granted to national market system plans (or provisions thereof) may not exceed 120 days in length.

<sup>1</sup> A company might not be prepared to elect to be subject to Sections 55 through 65 of the Investment Company Act of 1940 because its capital structure or management compensation plan is not yet in compliance with the requirements of those sections.

- a. the initial aggregate capacity projections for all Participants;
- b. the percentage of capacity requirements attributable to that Participant; and
- c. the amount of any projected excess capacity or any projected deficit capacity.

(SIAC determines the excess or deficit by comparing the capacity that the then existing systems under the Plans can provide and the aggregate projected capacity needs of the Participants.)

3. Each Participant will then notify the Processor of its final projected capacity needs.

4. Based on the information that SIAC provides, CTA and the CQ Operating Committee will determine and advise SIAC of any increase or decrease that they propose to make to the capacity of their respective systems. However, in directing SIAC to make any proposed change, the Participants must cause the system to have no less capacity than the capacity necessary to meet the aggregate projected capacity requirements for the system for all Participants.

5. SIAC will then submit to each Participant a proposal for increasing or decreasing total system capacity and each Participant's proportionate share of the estimated costs for implementing any change. Each Participant's proportionate share of the costs will reflect that Participant's percentage of the final projected capacity requirements for all Participants.

6. SIAC will bill each Participant directly and each Participant will pay SIAC for the services that SIAC renders to it. The cost of the services for each Participant will be its proportionate share of the total cost to all of the Participants.

7. Each Participant will be entitled to use its proportionate share of the final capacity requirements of all Participants and, at no extra cost, of any excess capacity. If the Processor determines that a Participant is using more than its proportionate share of the aggregate capacity and the excess capacity, that Participant may be subject to a fine. The proceeds from any such fine will be distributed to each of the other Participants in accordance with their proportionate shares.

#### *Intra-Cycle Capacity Transfers:*

1. In between the semi-annual capacity planning cycles, a Participant may seek to increase or decrease the amount of capacity available to it by notifying SIAC of its desire for more or less capacity. Under those circumstances, a Participant may purchase additional capacity only if another Participant has submitted to

SIAC an unfilled request to sell a portion of its capacity or if excess capacity exists in the system at that time. A Participant may sell some of its capacity only if another Participant has submitted to SIAC an unfilled request to purchase additional capacity.

2. If SIAC is able to match Participants' requests to buy and sell capacity within a planning cycle, SIAC will effect the sale for the Participants without revealing either Participant's identity.

3. If a Participant determines to acquire available excess capacity, SIAC shall adjust each Participant's proportionate share of system costs based on the new amount of capacity available to the Participant acquiring the available excess capacity.

4. On a periodic basis, SIAC will determine and inform each Participant of the total amount of the system capacity currently available, whether it is available from available excess capacity or from a Participant that seeks to sell capacity.

Under this plan, SIAC will not disclose to any Participant:

- 1. The initial or final projected capacity requirements of any other Participant;
- 2. The percentage of the aggregate amount of capacity attributable to any other Participant; or
- 3. Any other Participant's between-planning-cycles request to increase or decrease capacity.

The Participants requested that the proposed amendments to the Plans become effective summarily upon publication of notice of the proposed amendments, on a temporary basis not to exceed 120 days, so that the proposed new capacity planning process could be implemented on January 1, 2003, the date of the next capacity planning cycle.<sup>6</sup> The Commission put the proposed amendments to the Plans into effect summarily upon publication of the Notice on December 26, 2002.<sup>7</sup>

### **III. Discussion**

The Commission finds that the proposed amendments to the Plans are consistent with the requirements of the

Act and the rules and regulations thereunder,<sup>8</sup> and, in particular, Section 11A(a)(1)<sup>9</sup> of the Act and Rule 11Aa3-2 thereunder.<sup>10</sup>

The Commission notes that, pursuant to Rule 11Aa3-2(c)(4) under the Act<sup>11</sup>, it put the proposed 4th Amendment to the CTA Plan and the proposed 2nd Amendment to the CQ Plan into effect summarily upon publication of the proposed amendments. Rule 11Aa3-2(c)(4) under the Act provides that a proposed amendment may be put into effect summarily upon publication of such amendment, on a temporary basis not to exceed 120 days, if the Commission finds that such action is necessary or appropriate in the public interest, for the protection of investors and maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the Act. The Commission believes that summary effectiveness of the proposed amendments was necessary and appropriate for the new capacity planning process to take effect on January 1, 2003, the date of the next capacity planning cycle.

The Commission believes that an efficient capacity planning process is essential to the proper operation of CTA and administration of the CTA and CQ Plans. The Commission further believes that the proposed amendments to the Plans incorporating a new capacity planning process should address this need. The Commission notes that, under the new capacity planning process, each Participant will be required to submit its projected capacity needs directly to SIAC, and will not have to share its individual capacity needs with other Participants. Furthermore, SIAC will be responsible for providing each Participant with aggregates of both initial and final capacity projections for all Participants, and for directly billing each Participant for its proportionate share of the costs based on its percentage of the final projected capacity requirements for all Participants. The Commission finds that the proposed amendments incorporating this new capacity planning process into the Plans are consistent with Section 11A of the Act<sup>12</sup> and the rules and regulations thereunder.

<sup>8</sup> In approving the proposed plan amendments, the Commission has considered the proposed amendments' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>9</sup> 15 U.S.C. 78k-1(a)(1).

<sup>10</sup> 17 CFR 240.11Aa3-2.

<sup>11</sup> 17 CFR 240.11Aa3-2(c)(4).

<sup>12</sup> 15 U.S.C. 78k-1.

<sup>6</sup> Telephone conversation between Thomas E. Haley, Chairman, CTA, and Kathy A. England, Assistant Director, Sapna C. Patel, Attorney, Ian K. Patel, Attorney, Division of Market Regulation, Commission, on December 17, 2002. See also letter from Thomas E. Haley, Chairman, CTA, to Kathy A. England, Assistant Director, Division, Commission, dated December 16, 2002. The Commission notes that the original filing of the proposed amendments to the Plans incorrectly stated that the proposed amendments would take effect upon filing with the Commission because they are concerned solely with the administration of the Plans.

<sup>7</sup> See Notice, *supra* note 3.

#### IV. Conclusion

*It is therefore ordered*, pursuant to Section 11A of the Act<sup>13</sup> and paragraph (c)(2) of Rule 11Aa3-2<sup>14</sup> thereunder, that the proposed 4th Amendment to the CTA Plan and the proposed 2nd Amendment to the CQ Plan are approved on a permanent basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>15</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

[FR Doc. 03-4093 Filed 2-19-03; 8:45 am]

BILLING CODE 8010-01-P

#### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47345; File No. SR-Amex-2002-89]

##### Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change by the American Stock Exchange LLC Relating to Crossing Procedures for Clean Agency Crosses

February 11, 2003.

On November 5, 2002, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to amend Amex Rule 126(g), Commentary .02 to provide that orders of 5,000 shares or more for the account of a non-member organization may be crossed at a price at or within the bid or offer without being broken up by a specialist or Registered Trader acting as principal. The Amex filed an amendment to the proposed rule change on December 23, 2002.<sup>3</sup> The proposed rule change, as amended, was published for notice and comment in the **Federal Register** on January 7, 2003.<sup>4</sup> The Commission received no comments on the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the

rules and regulations thereunder applicable to a national securities exchange<sup>5</sup> and, in particular, the requirements of section 6 of the Act<sup>6</sup> and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with Section 6(b)(5) of the Act<sup>7</sup> in that the Rule is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Commission believes that the proposed rule change, while eliminating the opportunity for specialists and Registered Traders to effect a proprietary transaction to provide price improvement to one side of a clean cross or the other, preserves auction market principles by providing the possibility of price improvement (because members must follow Amex Rule 151 crossing procedures), and by requiring that members trade with other market interest having time priority at that price before trading with any part of the cross transaction. In addition, the Commission believes that the proposal will enhance competition among markets in the execution of agency crosses.

*It is therefore ordered*, pursuant to section 19(b)(2) of the Act<sup>8</sup>, that the proposed rule change, as amended (SR-AMEX-2002-89), be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>9</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

[FR Doc. 03-4045 Filed 2-19-03; 8:45 am]

BILLING CODE 8010-01-P

#### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47346; File No. SR-CBOE-2002-26]

##### Self Regulatory Organizations; Chicago Board Options Exchange, Inc.; Order Granting Approval to Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 1 to the Proposed Rule Change Increasing Position and Exercise Limits for Options on the DIAMONDS Trust

February 11, 2003.

#### I. Introduction

On May 20, 2002, the Chicago Board Options Exchange, Inc. ("CBOE") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to increase position and exercise limits for options on the DIAMONDS Trust ("DIA"). The proposed rule change was published for comment in the **Federal Register** on November 6, 2002.<sup>3</sup> The Commission received no comments on the proposal. On February 4, 2003, the CBOE filed Amendment No. 1 to the proposed rule change.<sup>4</sup> This order approves the proposed rule change, and notices and grants accelerated approval to Amendment No. 1 to the proposed rule change.

#### II. Description of the Proposal

The CBOE proposes to increase position and exercise limits for options on the DIA from 75,000 to 300,000 contracts on the same side of the market. Consistent with the reporting requirement for QQQ options, the Exchange will require that each member or member organization that maintains a position on the same side of the market in excess of 10,000 contracts in the DIA option class, for its own account or for the account of a customer report certain information. This data would include, but would not be limited to, the option position, whether

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 46743 (October 30, 2002), 67 FR 67673 (November 6, 2002).

<sup>4</sup> See Letter from Christopher R. Hill, Attorney II, Legal Division, CBOE, to Nancy Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission, dated February 3, 2003 ("Amendment No. 1"). In Amendment No. 1, the CBOE corrected erroneous text in CBOE Rule 4.13(b) to maintain the reporting requirement level for DIA options specified in CBOE Rule 4.13 at 10,000 contracts. Amendment No. 1 also corrected similar references to the reporting requirement level that were contained in the SEC Rule 19b-4 filing.

<sup>13</sup> 15 U.S.C. 78k-1.

<sup>14</sup> 17 CFR 240.11Aa3-2(c)(2).

<sup>15</sup> 17 CFR 200.30-3(a)(27).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See letter from Michael Cavalier, Associate General Counsel, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation, SEC, dated December 20, 2002, and enclosures ("Amendment No. 1"). Amendment No. 1 corrected a typographical error in the text of the proposed amendment.

<sup>4</sup> Securities Exchange Act Release No. 47113 (December 31, 2002), 68 FR 818.

<sup>5</sup> In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>6</sup> 15 U.S.C. 78f.

<sup>7</sup> 15 U.S.C. 78f(b)(5).

<sup>8</sup> 15 U.S.C. 78s(b)(2), proposed rule change, as amended (SR-Amex-2002-89), be, and hereby is, approved.

<sup>9</sup> 17 CFR 200.30-3(a)(12).

such position is hedged and if so, a description of the hedge and if applicable, the collateral used to carry the position. Exchange market-makers (including DPMs) would continue to be exempt from this reporting requirement as market-maker information can be accessed through the Exchange's market surveillance systems. In addition, the general reporting requirement for customer accounts that maintain a position in excess of 200 contracts will remain at this level for DIA options.<sup>5</sup>

### III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange<sup>6</sup> and, in particular, the requirements of section 6 of the Act<sup>7</sup> and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with section 6(b)(5) of the Act<sup>8</sup> because it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

Position and exercise limits serve as a regulatory tool designed to address potential manipulative schemes and adverse market impact surrounding the use of options. In the past, the Commission has stated that:

Since the inception of standardized options trading, the options exchanges have had rules imposing limits on the aggregate number of options contracts that a member or customer could hold or exercise. These rules are intended to prevent the establishment of options positions that can be used or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position. In particular, position and exercise limits are designed to minimize the potential for manipulations and for corners or squeezes of the underlying market. In addition such limits serve to reduce the possibility for disruption of the options market itself, especially in illiquid options classes.<sup>9</sup>

In general, the Commission has taken a gradual, evolutionary approach toward expansion of position and exercise limits. The Commission has been careful to balance two competing concerns when considering the

appropriate level at which to set position and exercise limits. The Commission has recognized that the limits must be sufficient to prevent investors from disrupting the market in the component securities comprising an index. These same concerns exist for the underlying portfolio securities held by exchange-traded fund shares, which track indexes such as the DIA. At the same time, the Commission has determined that limits must not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market makers from adequately meeting their obligations to maintain a fair and orderly market.<sup>10</sup>

The Commission has carefully considered the CBOE's proposal to increase position and exercise limits for DIA options. At the outset, the Commission notes that it still believes the fundamental purpose of position and exercise limits are being served by their existence. However, given the surveillance capabilities of the Exchange and the depth and liquidity in both the DIA options and the underlying cash market in DIAs, the Commission believes it is permissible to significantly raise position and exercise limits for DIA options without risk of disruption to the options or underlying cash markets. Specifically, the Commission believes that it is appropriate to increase position and exercise limits from 75,000 contracts to 300,000 contracts for DIA options for several reasons.

First, the Commission believes that the structure of the DIA options and the considerable liquidity of both the underlying cash and options market for DIA options lessen the opportunity for manipulation of this product and disruption in the underlying market that a lower position limit may protect against. In this regard, the CBOE notes that DIA, based on the Dow Jones Industrial Average, is among the most actively traded exchange-traded funds, averaging 4.5 million shares per day during the first six months of 2002. Moreover, the components comprising the fund are themselves among the most actively traded and widely held securities listed in the U.S. These factors provide support for higher limits for the DIA options and differentiate them from other equity options (including options on other exchange-traded fund shares).

Second, the Commission notes that current margin and risk-based haircut methodologies serve to limit the size of

positions maintained by any one account by increasing the margin and/or capital that a member must maintain for a large position held by itself or by its customer. Further, the CBOE, under CBOE Rules 4.13 and 12.10, may impose additional margin on options positions if it determines that this is warranted. The Commission believes that these financial requirements should help to address concerns that a member or its customer may try to maintain an inordinately large unhedged position in DIA options and will help to reduce risks if such a position is established.

Finally, the Commission believes that the reporting requirements imposed by the Exchange under CBOE Rule 4.13 will help protect against potential manipulation. The Exchange will require that each member or member organization that maintains a position on the same side of the market in excess of 10,000 contracts in the DIA option class, for its own account or for the account of a customer report certain information. This data would include, but would not be limited to, the option position, whether such position is hedged and if so, a description of the hedge and if applicable, the collateral used to carry the position. Exchange market-makers (including DPMs) would continue to be exempt from this reporting requirement as market-maker information can be accessed through the Exchange's market surveillance systems. In addition, the general reporting requirement for customer accounts that maintain a position in excess of 200 contracts will remain at this level for DIA options.<sup>11</sup> This information should help the CBOE to monitor accounts and determine whether it is necessary to impose additional margin for under-hedged positions, as provided under its rules.

In summary, the financial and reporting requirements noted above should allow the Exchange to detect and deter trading abuses arising from the increased position and exercise limits, and will also allow the Exchange to monitor large positions in order to identify instances of potential risk and to assess additional margin and/or capital charges, if deemed necessary. These requirements, coupled with the special trading characteristics of the DIA options and the underlying DIA noted above, warrant approval of the Exchange's proposal.<sup>12</sup>

<sup>11</sup> See CBOE Rule 4.13(a).

<sup>12</sup> Of course, the Commission expects that CBOE will take prompt action, including timely communication with the Commission and other marketplace self-regulatory organizations responsible for oversight of trading in the

<sup>5</sup> See CBOE Rule 4.13(a).

<sup>6</sup> In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>7</sup> 15 U.S.C. 78f.

<sup>8</sup> 15 U.S.C. 78f(b)(5).

<sup>9</sup> See Securities Exchange Act Release No. 39489 (December 24, 1997), 63 FR 276 (January 5, 1998).

<sup>10</sup> *Id.*

The Commission finds good cause for approving Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. Amendment No. 1 corrects an error in the proposed rule language and in the Rule 19b-4 rule filing to affirm that the reporting requirement level for DIA options will be set at 10,000 contracts. This is the current level under CBOE rules and remains unchanged. The Commission, therefore, believes that there is good cause to grant accelerated approval of Amendment No. 1, consistent with Section 6(b)(5) of the Act<sup>13</sup> and section 19(b)<sup>14</sup> of the Act.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 1, including whether it is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR-CBOE-2002-26 and should be submitted by March 13, 2003.

#### V. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act<sup>15</sup>, that the proposed rule change (SR-CBOE-2002-26), as amended, be and hereby is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>16</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03-4046 Filed 2-19-03; 8:45 am]

**BILLING CODE 8010-01-P**

underlying DIA, should any unanticipated adverse market effects develop due to the increased limits.

<sup>13</sup> 15 U.S.C. 78f(b)(5).

<sup>14</sup> 15 U.S.C. 78s(b).

<sup>15</sup> 15 U.S.C. 78s(b)(2).

<sup>16</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47353; File No. SR-NYSE-2002-58]

### Self-Regulatory Organizations; New York Stock Exchange; Order Approving Proposed Rule Change by New York Stock Exchange To Amend the Exchange's Automatic Execution Facility (NYSE Direct+)

February 12, 2003.

On November 1, 2002, the New York Stock Exchange ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to amend NYSE Rule 1005 to permit entry of limit orders up to 1,099 shares within 30 seconds for an account in which the same person has an interest, provided that the orders are entered from different terminals and that the member or member organization responsible for the entry of the orders to the trading floor ("Floor") has procedures to monitor compliance with the separate terminal requirement. On December 10, 2002, the rule proposal was published for comment in the **Federal Register**.<sup>3</sup> The Commission received 103 comments generally in favor of the proposed rule change. This order approves the proposed rule.

#### I. Description of the Proposed Rule Change

The NYSE Direct+ pilot<sup>4</sup> provides for the automatic execution of limit orders of 1099 shares or less (known as an "NX order" or auto ex order) against trading interest reflected in the Exchange's published quotation. It is not mandatory that all limit orders of 1099 shares be entered as NX orders; rather, the member organization entering the order,

or its customer if enabled by the member organization, can choose to enter an NX order when such member organization (or customer) believes that the speed and certainty of an execution at the Exchange's published bid or offer price is in its customer's best interest.

NYSE Rule 1005 currently provides that an NX order for any account in which the same person is directly or indirectly interested may only be entered at 30 second intervals. The restriction against the same customer entering an order within 30 seconds focuses on the identity of the ultimate beneficial owner of an account. Thus, an order cannot be entered for the same beneficial owner within 30 seconds. According to the NYSE, the purpose of this restriction is to limit the ability of a trader to circumvent the restriction on order size by breaking a large order into smaller components and repetitively entering them to exhaust liquidity at the published bid or offer price. The restriction in NYSE Rule 1005 applies across an entire firm, even if separate traders are making independent decisions with respect to an account in which the firm has an interest.

The Exchange is proposing to amend NYSE Rule 1005 to permit entry of NX orders within 30 seconds for an account in which the same person has an interest, provided that the orders are entered from different terminals and that the member or member organization responsible for the entry of the orders to the Floor has procedures to monitor compliance with the separate terminal requirement. Such procedures, at a minimum, must require member organization compliance departments to review patterns of order entry from individual terminals on a periodic basis to ensure compliance with the 30 second requirement.

#### I. Summary of Comments

The Commission received 103 comment letters generally supporting the proposed amendment to NYSE Direct +.<sup>5</sup> Many commenters stated that

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 46943 (December 4, 2002), 67 FR 75893.

<sup>4</sup> See Securities Exchange Act Release No. 43767 (December 22, 2000), 66 FR 834 (January 4, 2001) (SR-NYSE-2000-18) (approving the NYSE Direct + pilot). The one-year pilot was subsequently extended for another year in Securities Exchange Act Release No. 45331 (January 24, 2002), 67 FR 5024 (February 1, 2002) (SR-NYSE-2001-50). The pilot was recently extended through December 23, 2003. See Securities Exchange Act Release No. 46906 (November 25, 2002) 67 FR 72260 (December 4, 2002) (SR-NYSE-2002-47). The proposed rule change, if approved, would be part of the pilot and, thus, would expire on December 23, 2003 unless extended. Telephone conversation between Donald Siemer, Director, Market Surveillance, NYSE, and Sonia Patton, Special Counsel, Division of Market Regulation, Commission, December 3, 2002.

<sup>5</sup> A number of letters were from registered representatives and registered principals of Heartland Securities. These letters are identified individually. See letters to Jonathan G. Katz, Secretary, Commission, from Christopher Andrews, dated November 19, 2002 ("Andrews Letter"); Christopher Ball, undated ("Ball Letter"); Dror Ben-Aharon, undated ("Ben-Aharon Letter"); Alexander Benetti, dated November 19, 2002 ("Benetti Letter"); Patrick K. Blackburn, Executive Vice President, ABN-AMRO, dated December 23, 2002 ("ABN-AMRO Letter"); Eliav Bock, dated November 19, 2002 ("Bock Letter"); Arthur Brachowski, dated November 20, 2002 ("Brachowski Letter"); Thomas Bradshaw, undated ("Bradshaw Letter"); Blake C. Byczek, dated November 19, 2002 ("Byczek Letter"); Richard Cammarata, undated ("Cammarata Letter"); Coreina

Chan, dated November 19, 2002 ("Chan Letter"); Jireh Chao, Jr., undated ("Chao, Jr. Letter"); Jake Chun, undated ("Chun Letter"); Robert Cope, dated November 19, 2002 ("Cope Letter"); Daniel J. Cosenza, dated November 19, 2002 ("Cosenza Letter"); Dario Cosic, dated November 19, 2002 ("Cosic Letter"); Jay Crosby, undated ("Crosby Letter"); Glen Cutler, undated ("Cutler Letter"); Francis B. DeLuca, undated ("DeLuca Letter"); Brian Dershow, dated November 19, 2002 ("Dershow Letter"); Timothy K. Dolnier, undated ("Dolnier Letter"); David Dondero, undated ("Dondero Letter"); Michael Elmes, undated ("Elmes Letter"); Michael Elzahr, dated November 20, 2002 ("Elzahr Letter"); Tolga Erman, undated ("Erman Letter"); Michael Feeney, undated ("Feeney Letter"); Chris Freddo, undated ("Freddo Letter"); Elizabeth Goldstein, dated November 19, 2002 ("Goldstein Letter"); Jeff Gregario, undated ("Gregario Letter"); Cary S. Grill, dated November 19, 2002 ("Grill Letter"); Brian Gutbrod, undated ("Gutbrod Letter"); Charles William Hansford, dated November 19, 2002 ("Hansford Letter"); Zachary Hepner, November 18, 2002 ("Hepner Letter"); James Hochleutner, undated ("Hochleutner Letter"); Jonathan W. Hodges, dated November 20, 2002 ("Hodges Letter"); Edward E. Hong, undated ("Hong Letter"); Bradford O. Hotchkiss, dated November 18, 2002 ("Hotchkiss Letter"); Brian Ingram, dated November 20, 2002 ("Ingram Letter"); Aaron Israel, undated ("Israel Letter"); Jeremy Ives, dated November 19, 2002 ("Ives Letter"); Kevin Jahng, dated November 19, 2002 ("Jahng Letter"); Joel Jones, undated ("Jones Letter"); Matthew Keegan, dated November 19, 2002 ("Keegan Letter"); John Kernan, undated ("Kernan Letter"); Saeyoon Kim, dated November 19, 2002 ("Kim Letter"); Keith Kirstein, dated November 19, 2002 ("Kirstein Letter"); Gregory Kleiman, undated ("Kleiman Letter"); Eric P. Knight, undated ("Knight Letter"); David Kobin, dated November 18, 2002 ("Kobin Letter"); Aaron Kravitz, dated November 19, 2002 ("Kravitz Letter"); Ira Landsman, dated November 19, 2002 ("Landsman Letter"); Richard Lay, dated November 19, 2002 ("Lay Letter"); Samson Leung, undated ("Leung Letter"); Bronson C. Lingamfelter, undated ("Lingamfelter Letter"); Alex J. Lopez, undated ("Lopez Letter"); Michael Lucarello, undated ("Lucarello Letter"); Eugene Lum, dated November 19, 2002 ("Lum Letter"); Richard Lutz, undated ("Lutz Letter"); Jefferson Magat, dated November 19, 2002 ("Magat Letter"); Dax L. Mathews, dated November 19, 2002 ("Mathews Letter"); Kevin Medvin, ("Medvin Letter"); Robert Merrill, dated November 19, 2002 ("Merrill Letter"); Marc Miller, dated November 18, 2002 ("Miller Letter"); John J. Morgan, dated November 20, 2002 ("Morgan Letter"); Angelo Nicoletta, dated November 19, 2002 ("Nicoletta Letter"); Charles Nierling, dated November 19, 2002 ("Nierling Letter"); Michael O'Malley, dated November 20, 2002 ("O'Malley Letter"); Robert L. Oliver, Jr., November 17, 2002 ("Oliver, Jr. Letter"); Chris M. Paper, undated ("Paper Letter"); Boris Piskun, dated November 19, 2002 ("Piskun Letter"); Tal Plotkin, dated November 20, 2002 ("Plotkin Letter"); Frank Raffaele, dated November 18, 2002 ("F. Raffaele Letter"); John J. Raffaele, dated November 18, 2002 ("J. Raffaele Letter"); Richard Rebatta, dated November 18, 2002 ("Rebatta Letter"); John Schmidt, dated November 18, 2002 ("Schmidt Letter"); Matthew Schroeder, November 19, 2002 ("Schroeder Letter"); Jonathan Schuldenfrei, dated November 20, 2002 ("Schuldenfrei Letter"); David Schwarz, dated November 18, 2002 ("Schwarz Letter"); Drew Aaron Segal, dated November 19, 2002 ("Segal Letter"); Sinan Selcuk, dated November 19, 2002 ("Selcuk Letter"); Tal Sharon, dated November 20, 2002 ("Sharon Letter"); Theodore Siegel, dated November 20, 2002 ("Siegel Letter"); Dan Solomon, dated November 20, 2002 ("Solomon Letter"); Douglas Song, dated November 19, 2002 ("Song Letter"); Doug Squires, dated

proposed rule change would level the playing field between large and small firms<sup>6</sup> and allow greater access to the NYSE floor.<sup>7</sup> Specifically, one commenter noted that "[w]hile larger firms have NYSE floor brokers and hence direct access to the liquidity of the market and exposure to block orders, smaller firms must rely on the DOT system and Direct Plus."<sup>8</sup> Commenters also stated that the proposal would provide greater transparency and liquidity in the market place.<sup>9</sup> Other comments stated that the proposed amendment would increase speed of executions.<sup>10</sup> Finally, many commenters stated that traders at a firm who make independent decisions should not be considered to be "one firm" for purposes of complying with the 30 second restriction in NYSE Rule 1005.<sup>11</sup>

### III. Discussion

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>12</sup> Specifically, the Commission believes the proposed rule change is consistent with section 6(b)(5)

November 19, 2002 ("Squires Letter"); Igor Stancevic, dated November 19, 2002 ("Stancevic Letter"); Joe Tan, dated November 20, 2002 ("Joe Letter"); Howard Teitelman, dated November 19, 2002 ("Teitelman Letter"); Harlan Thompson, undated ("Thomson Letter"); Richard J. Travers III, dated November 19, 2002 ("Travers III Letter"); Michael W. Vaughn, dated November 19, 2002 ("Vaughn Letter"); Isaak Volodarsky, dated November 19, 2002 ("Volodarsky Letter"); Eric Walania, dated November 20, 2002 ("Walania Letter"); Alexander Wang, dated November 20, 2002 ("Wang Letter"); Sean Ward, dated November 19, 2002 ("Ward Letter"); Matthew Weinshall, dated November 20, 2002 ("Weinshall Letter"); Joshua Weintraub, dated November 19, 2002 ("Weintraub Letter"); Scott Westrick, dated November 19, 2002 ("Westrick Letter"); Travis P. Whitten, undated ("Whitten Letter"); Jimmie E. Williams, dated November 19, 2002 ("Williams Letter"); Kevin Yang, dated November 20, 2002 ("Yang Letter"); Paul Yiacas, undated ("Yiacas Letter"); and Daniel You, dated November 19, 2002 ("You Letter").

<sup>6</sup> See e.g., Solomon Letter; Landsman Letter; Sharon Letter; Knight Letter; Jahng Letter; Hochleutner Letter; Chao, Jr. Letter; Dershow Letter; Cammarata Letter; Cosenza Letter; and Weinshall Letter.

<sup>7</sup> See e.g., Chan Letter; J. Raffaele Letter; Volodarsky Letter; Plotkin Letter; Erman Letter; and Tan Letter.

<sup>8</sup> See Weinshall Letter.

<sup>9</sup> See e.g., Feeney Letter; Squires Letter; Stancevic Letter; Miller Letter; Vaughn Letter; Paper Letter; and Whitten Letter.

<sup>10</sup> See e.g., Jones Letter; Piskun Letter; Cosic Letter; Schroeder Letter; Westrick Letter; and Freddo Letter.

<sup>11</sup> See e.g., Selcuk Letter; Kravitz Letter; Lay Letter; Dolnier Letter; and Elzahr Letter.

<sup>12</sup> The Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

of the Act,<sup>13</sup> which requires among other things, that the rules of the Exchange are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to perfect the mechanism of a free and open market and national market system, and in general to protect investors and the public interest. The Commission believes that the proposed rule change is a reasonable expansion of the Direct + pilot and should allow individual traders greater flexibility and access to the trading interest reflected in the Exchange's published quotation. In addition, the Commission believes that the separate terminal requirement should help to ensure that traders are not circumventing the restriction on order size. The Commission notes that the Exchange has represented that it will surveil for compliance with this requirement when conducting periodic reviews of member organizations.

### IV. Conclusion

*It is therefore ordered*, pursuant to section 19(b)(2) of the Act,<sup>14</sup> that the proposed rule change (SR-NYSE-2002-58) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>15</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03-4044 Filed 2-19-03; 8:45 am]

**BILLING CODE 8010-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47352; File No. SR-PCX-2003-06]

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. To Amend the Price Criteria for Securities That Underlie Options Traded on the Exchange

February 11, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act"),<sup>1</sup> and Rule 19b-4

<sup>13</sup> 15 U.S.C. 78f(b)(5).

<sup>14</sup> Id.

<sup>15</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

thereunder,<sup>2</sup> notice is hereby given that on February 10, 2003, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to amend PCX Rule 3.6 in order to amend its pricing requirement for securities that underlie options traded on the Exchange ("underlying security"). The text of the proposed rule change follows. Additions are in *italics*. Deleted text is in brackets.

#### **Rules of the Board of Governors**

Rule 3.6. The underlying securities of option contracts traded on the Exchange shall be approved for Exchange transactions by the Board of Governors following the recommendation of the Options Listing Committee. In approving underlying securities, both the Options Listing Committee and the Board shall give due regard to, and the Board shall promulgate guidelines relative to, the following factors:

- (a)—No change.
- (1)–(3)—No change.

(4) [Either (i) the market price per share of the underlying security will have been at least \$7.50 for the majority of business days during the three calendar months preceding the date of selection, as measured by the lowest closing price recorded in any market in which the underlying security traded on each of the subject days;] (A) *If the underlying security is a "covered security" as defined under Section 18(b)(1)(A) of the Securities Act of 1933, the market price per share of the underlying security has been at least \$3.00 for the previous five consecutive business days preceding the date on which the Exchange submits a certificate to the Options Clearing Corporation for listing and trading. For purposes of this rule, the market price of such underlying security is measured by the closing price reported in the primary market in which the underlying security is traded.*

(B) *If the underlying security is not a "covered security", the market price per share of the underlying security has been at least \$7.50 for the majority of*

*business days during the three calendar months preceding the date of selection, as measured by the lowest closing price reported in any market in which the underlying security traded on each of the subject days, or [(ii)](a) the underlying security meets the guidelines for continued listing in Rule 3.7; (b) options on such underlying security are traded on at least one other registered national securities exchange; and (c) the average daily trading volume for such options over the last three (3) calendar months preceding the date of selection has been at least 5,000 contracts; and*

- (5)—No change.
  - (b)–(c)—No change.
- Commentary:  
.01–.04—No change.  
.05 (a)–(c)—No change.

(d) In the case of a Restructured Transaction that satisfies either or both of the conditions of subsections (a)(1) and (a)(2) to this Commentary .05 in which shares of a Restructured Security are sold in a public offering or pursuant to a rights distribution:

- (i)—No Change.
  - (ii) the exchange may certify that the market price of the Restructure Security satisfies the requirement of Rule 3.6(a)(4) by relying on the market price history of the Original Security prior to the ex-date for the Restructuring Transaction in the manner described by subsection (a) to this Commentary .05, but only if the Restructure Security has traded "regular way" on an exchange or automatic quotation system for at least five trading days immediately preceding the date of selection, and at the close of trading on each trading day preceding the date of selection, as well as the opening of trading on the date of selection the market price of the Restructure Security was at least \$7.50; or, if the Restructure Security is a Covered Security as defined in paragraph (a)(4) above, the market price of the Restructure Security was at least \$3.00; and
  - (iii)—No change.
- .06–.07—No change.

### **II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of

the most significant aspects of such statements.

#### **A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

##### **1. Purpose**

The Exchange proposes to amend its pricing requirement for underlying securities. Currently, PCX Rule 3.6 requires that the market price per share of any underlying security must be at least \$7.50 for the majority of business days during the three calendar months preceding the date of selection of an option class, as measured by the lowest closing price reported in any market in which the underlying security traded on each of the subject days.

The Exchange now proposes to amend Rule 3.6 to provide that, for underlying securities that are deemed Covered Securities, as defined under section 18(b)(1)(A) of the Securities Act of 1933 ("1933 Act"),<sup>3</sup> the closing market price of the underlying security must be at least \$3.00 per share for the five previous consecutive business days prior to the date on which PCX submits an option issue certification. For underlying securities that are not Covered Securities, the Exchange states that the current \$7.50 price per share requirement would continue to apply.

When the \$7.50 price requirement was first implemented, the listed options market was in its infancy. Now more than twenty-eight years after the PCX first started trading listed options, the Exchange states the listed options market is a mature market with sophisticated investors. The Exchange does not believe that this particular criteria serves to accomplish its presumed intended purpose, *i.e.*, to prevent the proliferation of option issues on overlying securities that lack liquidity needed to maintain fair and orderly markets. The Exchange states that it now seeks to move away from what it believes is a paternalistic approach to listing standards and allow the desires of its customers and the workings of the marketplace to determine the securities on which the Exchange will list options.

In determining to list any number of new option classes, the Exchange must

<sup>3</sup> Section 18(b)(1)(A) of the 1933 Act provides that, "(a) security is a covered security if such security is—listed, or authorized for listing, on the New York Stock Exchange or the American Stock Exchange, or listed, or authorized for listing, on the National Market System of the Nasdaq Stock Market \* \* \* 15 U.S.C. 77r(b)(1)(A). The term Covered Security, for the operation of proposed amendments to Rule 3.6 and Commentary .05 herein, would not include those securities defined under Section 18(b)(1)(B) of the 1933 Act. 15 U.S.C. 77r(b)(1)(B).

<sup>2</sup> 17 CFR 240.19b-4.



ensure that its own systems and those of the Options Price Reporting Authority ("OPRA") have the capacity to handle the potential increased capacity requirements. Also, due to recent trends in the securities markets, there has been a marked increase in the number of underlying securities that, but for the pricing standard, would otherwise qualify for options listing on the Exchange. The Exchange states that changing the pricing standard to the proposed \$3.00 market price per share requirement would allow the Exchange to evaluate whether to list options on a greater number of classes without compromising investor protection.

The Exchange notes that although this proposal amends the closing market price for an underlying security which is deemed a Covered Security, as well as the time period for which it must trade at that price prior to it being listed on the Exchange, the Exchange will continue to maintain its initial listing standards. The Exchange does not propose to amend any of the other criteria in PCX Rule 3.6, including the requirements that: there must be a minimum of 7,000,000 shares of the underlying security owned by public investors; there must be a minimum of 2,000 holders of the underlying security; and, that there must be a trading volume of at least 2,400,000 shares in the preceding twelve months. Additionally, by requiring the underlying security to be listed on the New York Stock Exchange, Inc., American Stock Exchange LLC ("Amex"), or Nasdaq National Market System ("Nasdaq"),<sup>4</sup> the Exchange states that this would ensure that the underlying security meets the highest listing standards in the securities industry. However, if the underlying security does not qualify as a Covered Security, the \$7.50 market price per share standard still will apply.

The Exchange believes that the proposed \$3.00 market price per share standard is also consistent with the guideline price in the PCX Delisting Criteria Rule 3.7 which is used to determine whether an underlying security previously approved for Exchange options transactions no longer meets the requirements for the continuance of approval. Commentary .02 to PCX Rule 3.7 sets a \$3 market price per share as the threshold for determining whether the Exchange may continue listing and trading options on an underlying security that was previously approved for options trading under PCX Rule 3.6. As long as a \$3.00 standard is recognized as an acceptable pricing standard for options trading,

albeit as a standard for continued listing, the Exchange believes that the proposed \$3.00 should be the threshold standard for initial listing standards as well.

The Exchange also proposes, as a safeguard against price manipulation, that the underlying security have a closing market price of at least \$3.00 per share for the previous five consecutive business days preceding the date on which the Exchange submits a certificate to the Options Clearing Corporation for listing and trading. The market price of such underlying security would be measured by the closing price reported in the primary market in which the underlying security is traded. The Exchange believes that a "look back" period of five consecutive days would provide a sufficient measure of protection from any attempts to manipulate the market price of the underlying security.

The Exchange also believes that the proposed rule change would encourage the delisting of inactive option classes, particularly those classes in which the market price of the underlying security is below \$7.50. Currently, a Lead Market Maker ("LMM") on the Exchange to whom an option class has been allocated may be reluctant to delist an inactive option class if the market price of the underlying security is below \$7.50 because once delisted, the Exchange's current initial listing criteria must be met to re-list the option class, including the requirement that the market price per share of the underlying security be at least \$7.50 for the majority of business days during the preceding three months. The Exchange also notes that the Commission recently granted PCX approval to list additional series on an option class even though the market price of the underlying security is below \$3, provided that at least one other options exchange trades the series to be added, and at the time the other options exchange added that series, it met the requirements to add new series, including the \$3 price requirement.<sup>5</sup>

The proposed \$3 price standard and the five-day look-back period would provide a reliable test for stability and, at the same time, presents a more

reasonable time period for qualifying the price of an underlying security. The Exchange further believes that this proposed abbreviated qualification period, in combination with the Exchange's existing quarterly delisting program,<sup>6</sup> would contribute to reducing unnecessary quote traffic.

Finally, for the purposes of consistency within the PCX Rules, the Exchange proposes to amend PCX Rule 3.6 Commentary .05 with respect to Restructure Securities. Currently, Commentary .05 provides a method to certify that the market price of a Restructure Security satisfies the pricing requirement of PCX Rule 3.6 and specifically references the \$7.50 market price per share. In order to make the Rule consistent with the pricing standard change of this proposal, the amended rule would reflect that the market price standard for Restructure Securities also will be reduced from \$7.50 to \$3.00 as long as the Restructure Security is a Covered Security.

## 2. Statutory Basis

The Exchange believes that the current proposal will allow the Exchange to provide investors with those options that are most useful and demanded by them without sacrificing any investor protection. As such, the Exchange believes that the proposed rule change is consistent with section 6(b) of the Act<sup>7</sup> in general and furthers the objectives of section 6(b)(5)<sup>8</sup> in particular in that it will promote just and equitable principles of trade; facilitate transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system; and protect investors and the public interest.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received with respect to the proposed rule change.

<sup>6</sup> The Exchange states that it maintains an active delisting program which requires the quarterly delisting of multiply listed option classes that do not trade more than 20 contracts per day on the Exchange.

<sup>7</sup> 15 U.S.C. 78f(b).

<sup>8</sup> 15 U.S.C. 78f(b)(5).

<sup>5</sup> See Securities Exchange Act Release No. 46406 (August 23, 2002), 67 FR 55446 (August 29, 2002) (approving SR-PCX-2002-51). The Exchange represents that these rules are consistent with similar rules regarding listing and maintenance standards of the American Stock Exchange LLC ("Amex"), International Securities Exchange, Inc. ("ISE"), Chicago Board of Options Exchange, Inc. ("CBOE") and the Philadelphia Stock Exchange, Inc. ("Phlx"). See Interpretation and Policy .02 to CBOE Rule 5.4; Commentary .02 to Amex Rule 916; Commentary .02 to Phlx Rule 1010; and ISE Rule 503(c).

<sup>4</sup> See 15 U.S.C. 77r(b)(1)(A).



### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change, as amended, has become effective pursuant to section 19(b)(3)(A) of the Act<sup>9</sup> and subparagraph (f)(6) of Rule 19b-4<sup>10</sup> thereunder because it does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate; and the Exchange has given the Commission written notice of its intention to file the proposed rule change at least five business days prior to filing. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Under Rule 19b-4(f)(6)(iii) of the Act,<sup>11</sup> the proposal does not become operative for 30 days after the date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest and the Exchange is required to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to filing. The Exchange has requested that the Commission waive the 30-day operative date and the five-day pre-filing notice requirement in order for it to implement the proposed rule change as quickly as possible. The Exchange contends that this proposed rule is substantially similar to comparable rules the Commission approved for the CBOE, which was published for public notice and comment.<sup>12</sup> As a result, the Exchange believes that the proposed rule change does not raise any new regulatory issues, significantly affect the protection of investors or the public interest, or impose any significant burden on competition. The Commission, consistent with the protection of investors and the public interest, has determined to waive the 30-day operative period as well as the

five-day pre-filing notice requirement,<sup>13</sup> and, therefore, the proposal is effective and operative upon filing with the Commission.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR-PCX-2003-06 and should be submitted by March 13, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>14</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03-4047 Filed 2-19-03; 8:45 am]

BILLING CODE 8010-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-47359; File No. SR-Phlx-2003-03]

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to the Automatic Execution of Eligible Orders During Locked Markets

February 12, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup>

<sup>13</sup> For purposes only of waiving the five-day pre-filing notice requirement and the 30-day operative period for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>14</sup> 17 CFR 200.30-3(a)(12)

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

notice is hereby given that on January 21, 2003, the Philadelphia Stock Exchange, Inc. ("Phlx" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has filed the proposal as a "non-controversial" rule change pursuant to section 19(b)(3)(A) of the Act,<sup>3</sup> and Rule 19b-4(f)(6) thereunder,<sup>4</sup> which renders the proposal effective upon filing with the Commission.<sup>5</sup> The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend Rule 1080, Philadelphia Stock Exchange Automated Options Market (AUTOM) and Automatic Execution System (AUTO-X),<sup>6</sup> to provide for the automatic execution of eligible orders during locked markets (*i.e.*, 2 bid, 2 offer). Below is the of the proposed rule change. Proposed new language is italicized. Proposed deletions are in [brackets].

Philadelphia Stock Exchange Automated Options Market (AUTOM) and Automatic Execution System (AUTO-X)

Rule 1080. (a)-(b) No change.

(c) (i)-(iii) No change.

(iv) Except as otherwise provided in this Rule, in the following circumstances, an order otherwise eligible for AUTO-X will instead be manually handled by the specialist:

(A) the Exchange's disseminated market is crossed (*i.e.*, 2 $\frac{1}{8}$  bid, 2 offer) [or locked (*i.e.*, 2 bid, 2 offer)], or crosses [or locks] the disseminated market of another options exchange;

(B)-(I) No change.

(d)-(j) No change.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

<sup>5</sup> The Phlx asked the Commission to waive the 5-day pre-filing requirement and the 30-day operative delay. See Rule 19b-4(f)(6)(iii). 17 CFR 240.19b-4(f)(6)(iii).

<sup>6</sup> AUTOM is the Exchange's electronic order delivery, routing, execution and reporting system, which provides for the automatic entry and routing of equity option and index option orders to the Exchange trading floor. Orders delivered through AUTOM may be executed manually, or certain orders are eligible for AUTOM's automatic execution feature, AUTO-X. Equity option and index option specialists are required by the Exchange to participate in AUTOM and its features and enhancements. Option orders entered by Exchange members into AUTOM are routed to the appropriate specialist unit on the Exchange trading floor. See Phlx Rule 1080.

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f)(6).

<sup>11</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>12</sup> See Securities Exchange Act Release No. 47190 (January 15, 2003), 68 FR 3072 (January 22, 2003) (approving SR-CBOE-2002-62).

Commentary: No change.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The purpose of the proposal is to increase automated options order handling by enabling the Exchange to automatically execute eligible inbound orders during a locked market (*i.e.*, 2 bid, 2 offer).<sup>7</sup>

Currently, Exchange Rule 1080(c)(iv)(A) provides that inbound orders otherwise eligible for automatic execution via AUTO-X will instead be manually handled by the specialist when the Exchange's disseminated market is crossed (*i.e.*, 2 $\frac{1}{8}$  bid, 2 offer) or locked, or crosses or locks the disseminated market of another options exchange.<sup>8</sup> The proposal would amend

Exchange Rule 1080(c)(iv)(A) to delete references to locked markets, such that all inbound orders that are otherwise eligible for automatic execution via AUTO-X would be automatically executed during locked markets. The Exchange believes that this should provide for the automatic execution of a greater number of eligible inbound orders than under the current rules. Orders received during crossed markets would continue to be handled manually by the specialist.

#### 2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirement under section 6(b)(5) of the Act<sup>9</sup> in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest by providing automatic executions for eligible orders during locked markets, which should result in a greater number of automatic executions for orders on the Exchange.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx does not believe that the proposed rule change will impose any inappropriate burden on competition.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days (or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest) after the date of the filing, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act<sup>10</sup> and Rule 19b-4(f)(6) thereunder.<sup>11</sup> At any time within

Settlement Order"). Pursuant to the Settlement Order, the Exchange adopted Rule 1080(c)(iv) to codify situations in which orders are handled manually. At this time, the Exchange is proposing to automatically execute eligible inbound orders in one particular situation (*i.e.*, during locked markets) that currently involves manual handling.

<sup>9</sup> 15 U.S.C. 78f(b)(5).

<sup>10</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>11</sup> 17 CFR 240.19b-4(f)(6).

60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act.

A proposed rule change filed under Rule 19b-4(f)(6) normally must not become operative prior to 30 days after the date of the filing. In addition, a self-regulatory organization filing a proposed rule change under Rule 19b-4(f)(6)(iii) normally must give the Commission written notice of its intent to file the proposed rule change five days prior to the date of filing. However, Rule 19b-4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive both the five-day pre-filing requirement and designate that the proposed rule change become operative immediately to allow automatic execution of eligible orders during locked markets.

The Commission believes it is consistent with the protection of investors and the public interest to waive the five-day pre-filing requirement and designate the proposal immediately operative.<sup>12</sup> Accelerating the operative date and waiving the pre-filing requirement should permit the Exchange to provide for a greater number of eligible inbound orders to be automatically executed during locked markets. The proposed rule change should help provide faster execution of certain eligible orders, while reducing the burden on the Exchange's specialists with respect to manual execution of these orders during locked markets. The proposal should benefit customers using the Auto-X system, as well as customers whose orders are residing in the Exchange's book during locked markets because more orders should be more timely executed during locked markets.

Furthermore, the Commission notes that Phlx's proposal is similar to proposed rule changes that were approved previously by the Commission.<sup>13</sup> Thus, the proposed rule

<sup>12</sup> For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>13</sup> See Securities Exchange Release Nos. 42167 (November 22, 1999), 64 FR 66954 (November 30, 1999) (order approving CBOE Rule 6.8, Interpretation and Policy .02(b)(iv)); and 45032 (November 6, 2001), 66 FR 57145 (November 14, 2001) (order relating to PCX's Automatic Execution System). Pursuant to telephone conversation

<sup>7</sup> The Exchange notes that it has previously filed to allow for the automatic execution of eligible inbound customer orders during a locked market. See File No. SR-Phlx-2002-86. Because other proposed rule changes included in that filing remain under discussion between Exchange staff and Commission staff as of the filing date of the instant proposal, the Exchange is submitting the instant proposed rule change in order to expedite the automatic execution of eligible orders during locked markets. Upon the completion of discussions with Commission staff, the Exchange intends to amend File No. SR-Phlx-2002-86 to, *inter alia*, delete from that proposal those provisions that are included in the instant proposal.

<sup>8</sup> Under the *Order Instituting Public Administrative Proceedings Pursuant to Section 19(h)(1) of the Securities Exchange Act of 1934, Making Findings and Imposing Sanctions*, the Exchange (and the other respondent exchanges, the American Stock Exchange LLC, the Chicago Board Options Exchange, and the Pacific Exchange, Inc.) were required to adopt new, or amend existing, rules concerning automatic quotation and execution systems which specify the circumstances, if any, under which automated execution systems be disengaged or operated in any manner other than the normal manner set forth in the Exchange's rules and require the documentation of the reasons for each decision to disengage an automatic execution system or operate it in any manner other than the normal manner. See Securities Exchange Act Release No. 43268 (September 11, 2000), Administrative Proceeding File 3-10282 (the "

change concerns issues that previously have been the subject of full comment periods pursuant to section 19(b) of the Act.<sup>14</sup> Accordingly, the Commission designates the proposed rule change to be effective and operative upon filing with the Commission.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference section, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR-Phlx-2003-03 and should be submitted by March 13, 2003.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.<sup>15</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

[FR Doc. 03-4048 Filed 2-19-03; 8:45 am]

BILLING CODE 8010-01-P

#### DEPARTMENT OF STATE

[Public Notice 4264]

##### Advisory Committee on International Economic Policy; Notice of Open Meeting

The Advisory Committee on International Economic Policy (ACIEP) will meet from 9 a.m. to 12 noon on Thursday, March 6, 2003 in Room 1105 at the U.S. Department of State, 2201 C Street NW., Washington, DC 20520. The

meeting will be hosted by Assistant Secretary of State for Economic and Business Affairs E. Anthony Wayne and Committee Chairman R. Michael Gadbow.

The ACIEP serves the U.S. Government in a solely advisory capacity concerning issues and problems in international economic policy. Proposed topics for the March 6 meeting are: economic security, investment issues, and a draft UN Convention Against Corruption.

The public may attend these meetings as seating capacity allows. The media are welcome but discussions are off the record. Admittance to the Department of State building is by means of a pre-arranged clearance list. In order to be placed on this list, please provide your name, title, company or other affiliation if appropriate, social security number, date of birth, and citizenship to the Advisory Committee Executive Secretariat by fax (202) 647-5936 (Attention: Gwendolyn Jackson); Tel: (202) 647-0847; or email: [jacksongl@state.gov](mailto:jacksongl@state.gov) by March 4, 2003.

On the date of the meeting, persons who have pre-registered should come to the 23rd Street entrance. One of the following valid means of identification is required for admittance: a U.S. driver's license with photo, a passport, or a U.S. Government identification.

For further information about the meeting, please contact Eliza Koch, ACIEP Secretariat, Office of Economic Policy and Public Diplomacy, Economic Bureau, U.S. Department of State, Room 3526, 2201 C Street NW., Washington, DC 20520, Tel (202) 647-1310.

Dated: February 14, 2003.

**Daniel A. Clune,**

Director, Office of Economic Policy and Public Diplomacy, Department of State.

[FR Doc. 03-4099 Filed 2-19-03; 8:45 am]

BILLING CODE 4710-07-P

#### DEPARTMENT OF TRANSPORTATION

##### Coast Guard

[USCG 2003-14496]

##### Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers 2115-0586, 2115-0053, 2115-0025, and 2115-0007

**AGENCY:** Coast Guard, DOT.

**ACTION:** Request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of four

Information Collection Requests (ICRs). The ICRs comprise (1) Marine Occupational Health and Safety Standards for Benzene—46 CFR part 197, subpart C, (2) Request for Designation and Exemption of Oceanographic Research Vessels, (3) Oil Record Book for Ships, and (4) Application for Vessel Inspection and Waiver. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

**DATES:** Comments must reach the Coast Guard on or before April 21, 2003.

**ADDRESSES:** To make sure that your comments and related material do not enter the docket [USCG 2003-14496] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Facility at 202-493-2251.

(4) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

The Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICRs are available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (G-CIM-2), U.S. Coast Guard Headquarters, room 6106 (Attn: Barbara Davis), 2100 Second Street SW., Washington, DC 20593-0001. The telephone number is 202-267-2326.

**FOR FURTHER INFORMATION CONTACT:** Barbara Davis, Office of Information Management, 202-267-2326, for questions on this document; or Dorothy Beard, Chief, Documentary Services

<sup>14</sup> 15 U.S.C. 78s(b).

<sup>15</sup> 17 CFR 200.30-3(a)(12).

Division, U.S. Department of Transportation, 202-366-5149, for questions on the docket.

#### Request for Comments

The Coast Guard encourages interested persons to submit comments. Persons submitting comments should include their names and addresses, identify this document [USCG 2003-14496], and give the reasons for the comments. Please submit all comments and attachments in an unbound format no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped self-addressed postcards or envelopes.

#### Information Collection Requests

1. *Title:* Marine Occupational Health and Safety Standards for Benzene—46 CFR part 197, subpart C.

*OMB Control Number:* 2115-0586.

*Summary:* To protect marine workers from exposure to toxic benzene vapor, the Coast Guard implemented 46 CFR part 197, subpart C.

*Need:* This information collection is vital to verifying compliance.

*Respondents:* Owners and operators of vessels.

*Frequency:* On occasion.

*Burden:* The estimated burden is 59,766 hours a year.

2. *Title:* Request for Designation and Exemption of Oceanographic Research Vessels.

*OMB Control Number:* 2115-0053.

*Summary:* 46 U.S.C. 2113 authorizes the Secretary of Transportation to exempt Oceanographic Research Vessels, by rule, from certain parts of Subtitle II of Title 46, Shipping, of the United States Code, concerning vessels and seamen.

*Need:* This information is necessary to ensure that a vessel qualifies for exemption.

*Respondents:* Owners or operators of vessels.

*Frequency:* On occasion.

*Burden:* The estimated burden is 21 hours a year.

3. *Title:* Oil Record Book for Ships.

*OMB Control Number:* 2115-0025.

*Summary:* The Act to Prevent Pollution from Ships (APPS) and the International Convention for Prevention of Pollution from Ships, 1973, as modified by the 1978 Protocol relating thereto (MARPOL 73/78), require the entry into an Oil Record Book (CG-4602A) of information about oil carried as cargo or fuel. The maintenance of the Book constitutes the collection of information. The requirement for it appears at 33 CFR 151.25.

*Need:* This information helps to verify sightings of actual violations of the APPS, to determine the level of compliance with MARPOL 73/78, and to reinforce the provisions against discharge.

*Respondents:* Operators of vessels.

*Frequency:* On occasion.

*Burden:* The estimated burden is 29,048 hours a year.

4. *Title:* Application for Vessel Inspection and Waiver.

*OMB Control Number:* 2115-0007.

*Summary:* The collection of information requires the owner, operator, agent, or master of a vessel to apply in writing to the Coast Guard before the commencement of the inspection for certification, or when, in the interest of national defense, a waiver from the requirements of navigation and vessel inspection seems desirable.

*Need:* 46 U.S.C. 3306 and 3309 authorize the Coast Guard to establish rules to protect life, property, and the environment by inspecting vessels. The reporting requirements of the Application for Inspection of U.S. Vessels and the Application for Waiver and Waiver Order are part of the Coast Guard's Marine Safety Program.

*Respondents:* Owners, operators, agents, or masters of vessels, or interested Federal agencies.

*Frequency:* On occasion, yearly, or on a 5-year cycle.

*Burden:* The estimated burden is 677 hours a year.

Dated: February 12, 2003.

**Clifford I. Pearson,**

*Rear Admiral, U.S. Coast Guard, Director of Information and Technology.*

[FR Doc. 03-4147 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-15-P**

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

[USCG-2003-14495]

### Towing Safety Advisory Committee

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of meetings.

**SUMMARY:** The Towing Safety Advisory Committee (TSAC) and its working groups will meet as required to discuss various issues relating to shallow-draft inland and coastal waterway navigation and towing safety. All meetings will be open to the public.

**DATES:** TSAC will meet on Wednesday, March 19, 2003, from 8 a.m. to 12:30 p.m. The working groups will meet on Tuesday, March 18, 2003, from 8 a.m. to 3:30 p.m. These meetings may close

early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before February 28, 2003. Requests to have a copy of your material distributed to each member of the Committee or working groups should reach the Coast Guard on or before February 28, 2003.

**ADDRESSES:** On March 19, 2003, TSAC will meet in the East and West Meeting Rooms, the Hotel Monteleone hotel, 214 Rue Royale New Orleans, Louisiana 70130-2201. On March 18, 2003, the working groups will meet in the Vieux Carre Room at the same address and then, if necessary, move to separate spaces designated at that time. Send written material and requests to make oral presentations to Mr. Gerald P. Miente, Commandant (G-MSO-1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001. This notice and a draft task statement are available on the Internet at <http://dms.dot.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gerald P. Miente, Assistant Executive Director, or Petty Officer Bryan Wick, telephone 202-267-0214, fax 202-267-4570, or e-mail at: [gmiente@comdt.uscg.mil](mailto:gmiente@comdt.uscg.mil).

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

### Agenda of Committee Meeting

The agenda tentatively includes the following:

- (1) Status Report of the Crew Alertness Working Group;
- (2) Status Report of the Towing Vessel Regulatory Review Working Group;
- (3) Status Report of the Maritime Security Working Group and Consideration of any Recommendations to the Coast Guard Regarding Potential Rules;
- (4) Status Report of the Study Group on Adequacy of Navigation Lights for Inland River Barge Tows; and
- (5) Consideration of a draft Task Statement regarding the issue of travel, or "deadhead," time.

### Procedural

All meetings are open to the public. Please note that the meetings may close early if all business is finished. Members of the public may make oral presentations during the meetings. If you would like to make an oral presentation at a meeting, please notify the Assistant Executive Director no later than February 28, 2003. Written material for distribution at a meeting should reach the Coast Guard no later

than February 28, 2003. If you would like a copy of your material distributed to each member of the committee or working groups in advance of a meeting, please submit 17 copies to the Assistant Executive Director no later than February 28, 2003. You may also submit this material electronically to the e-mail address in **FOR FURTHER INFORMATION CONTACT**, no later than February 28, 2003.

#### **Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact the Assistant Executive Director as soon as possible.

Dated: February 12, 2003.

**Howard L. Hime,**

*Acting Director of Standards, Marine Safety, Security & Environmental Protection.*

[FR Doc. 03-4146 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-15-P**

## **DEPARTMENT OF TRANSPORTATION**

### **Coast Guard**

[USCG-2003-14500]

#### **Merchant Mariners' Documents: Forms and Procedures for Renewals and Issuances**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of policy.

**SUMMARY:** The Coast Guard suspended renewing and issuing Merchant Mariners' Documents (MMDs) using the previously issued form and has begun renewing and reissuing MMDs using a new form. The new MMD form is more tamper-resistant and facilitates verification of an MMD holder's identity, citizenship, and qualifications to work aboard U.S.-flagged vessels. MMDs in the new form will enhance maritime security.

**DATES:** The Coast Guard began renewing MMDs using the new form on February 3, 2003.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call Mr. Donald J. Kerlin, Deputy Director, Coast Guard National Maritime Center (NMC), (202) 493-1006.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

MMDs both serve as identity cards for merchant mariners and provide information about the mariners' professional qualifications. MMDs, in the previously issued form (CG-2838 [Rev. 7-94]), serve the second of these

purposes well enough; however, they no longer serve the first with sufficient confidence. The Coast Guard is replacing them using a new form (CG-2838 [Rev 09/02]) that will be issued through a more secure process. The Coast Guard will make every effort to effect a smooth and easy transition from the previously issued form to the new form. The Coast Guard will begin issuing MMDs in the new form to new applicants as soon as possible.

The Coast Guard also is considering whether to allow mariners to replace their previously issued MMDs with new MMDs on an accelerated basis, *i.e.*, at an earlier date than current expiration date. To ensure that only eligible mariners receive MMDs, the Coast Guard will conduct a criminal-record review of mariners seeking renewal or re-issuance of a previously issued MMD, or issuance of an original MMD. The review may include verification of identities; criminal histories; and sobriety (as gauged from, among other sources, the National Drivers' Register). This review will be consistent with applicable law and Coast Guard regulations set forth in Title 46, Code of Federal Regulations (46 CFR 12.02-4). Because of the importance of establishing positive proof of identity to facilitate the background investigation, it will be necessary for holders of, and applicants for, an MMD to be present at a Regional Examination Center (REC) to be fingerprinted.

Mariners may encounter delays incident to the new processes' going into practice and the delays may persist for some weeks. Holders and new applicants seeking re-issuance, renewal, and original issuance of their MMDs should inquire at their nearest REC, a list of which appears at 46 CFR 12.01-7, or contact Mr. Donald Kerlin at the National Maritime Center, 4200 Wilson Boulevard, Suite 630, Arlington, VA 22203-1804, (202) 493-1006.

#### **Authority**

46 U.S.C. 7301, 7302, 7303, 7304, 7305, 7503, 7505, and 49 CFR 1.46.

Dated: February 13, 2003.

**Kevin J. Eldridge,**

*Rear Admiral, Coast Guard, Assistant Commandant for Governmental and Public Affairs.*

[FR Doc. 03-4145 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-15-P**

## **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

#### **Harmonization Initiatives**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Federal Aviation Administration and the Joint Aviation Authorities will convene meetings to accept input from the public on the Harmonization Work Program. The Federal Aviation Administration and the Joint Aviation Authorities use the Harmonization Work Program to carry out a commitment to harmonize, to the maximum extent possible, various rules. These rules include the operation and maintenance of civil aircraft, and the standards, practices, and procedures governing the design materials, workmanship, and construction of civil aircraft, aircraft engines, and other components. The purpose of this meeting is to give the public an opportunity to provide input to the Harmonization Work Program. This notice announces the date, time, location, and procedures for the public meeting.

**DATES:** The public meeting will be held on March 4, 2003, starting at 10:30 a.m. Written comments are invited and must be received by February 24, 2003.

**ADDRESSES:** The public meeting will be held at Central Joint Aviation Authorities, 8-10 Statuussstraat, Hoofddorp, The Netherlands. Persons unable to attend the meeting may mail their comments in triplicate to: Florence Hamn, Federal Aviation Administration, Office of Rulemaking, ARM-200, 800 Independence Avenue, SW., Washington, DC 20591.

#### **FOR FURTHER INFORMATION CONTACT:**

Requests to attend and present a statement at the meeting or questions about the logistics of the meeting should be directed to Florence Hamn, Office of Rulemaking, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3625, telefax (202) 267-5075.

**SUPPLEMENTARY INFORMATION:** The Federal Aviation Administration and the Joint Aviation Authorities will convene meetings to accept input from the public on the Harmonization Work Program. On March 3, there will be an authorities only meeting that addresses various certification, operations, maintenance, and harmonization issues. The March 4 public meeting will begin at 10:30 a.m. and the agenda will include:

- Debrief on Items from Authorities only meeting of the Harmonization Management Team (HMT).

- Debrief on Operations/Maintenance/Licensing Harmonization Group specific items.

- Debrief on Certification Codes Harmonization Group specific items.

- FAA/JAA 20th International Conference, May 29–June 3, 2002.

- Review/Approval of Minutes of November 18–19 HMT meeting.

- Update on Airworthiness

- Rulemaking Prioritization Activities.

- Any Other Business.

Individuals wishing to attend and participate in the meetings must submit name, address, telephone/fax/email, and citizenship information to the person listed under the title **FOR FURTHER INFORMATION CONTACT** not later than February 24, 2003. The list of attendees must be submitted to the Joint Aviation Authorities before the meeting for security reasons and to prepare name badges that must be worn while in the building.

**Lodging Arrangements:** There are multiple hotels located near the meeting location. For further information about lodging, please contact the person listed under the title **FOR FURTHER INFORMATION CONTACT**.

#### Participation at the Meetings

The FAA should receive requests from persons who wish to present oral statements at the public meetings by February 24, 2003. Such requests should be sent to Florence Hamn as listed in the section titled **FOR FURTHER INFORMATION CONTACT** and should include a written summary of oral remarks to be presented, and an estimate of time needed for the presentation. Requests received after the date specified above will be scheduled if time is available; however, the name of those individuals may not appear on the written agenda.

The FAA will prepare a final agenda of speakers, which will be available at the meeting. Every effort will be made to accommodate as many speakers as possible. In addition, the time allocated to each speaker may be less than the amount of time requested.

#### Meeting Procedures

The following procedures are established to facilitate the meetings:

(1) There will be no admission fee or other charge to attend or to participate in the meeting. The meetings will be open to all persons who have requested in advance to present statements or who register on the day of the meeting subject to availability of space in the meeting room.

(2) There will be morning and afternoon breaks and lunch breaks.

(3) The meetings may adjourn early if scheduled speakers complete their statements in less time than currently is scheduled.

(4) An individual, whether speaking in a personal or a representative capacity for an organization, may be limited to a 10-minute statement. If possible, we will notify the speaker if more time is available.

(5) The FAA will try to accommodate all speakers. If the available time does not permit this, speakers generally will be scheduled on a first-come-first-served basis. However, the FAA reserves the right to exclude some speakers if necessary to present a balance of viewpoints and issues.

(6) Representatives of the FAA and JAA will preside over the meetings.

(7) The FAA and JAA will review and consider all material presented by participants at the meetings. Position papers or material presenting views or information related to proposed harmonization initiatives may be accepted at the discretion of the FAA and JAA presiding officers. The FAA requests that persons participating in the meetings provide five (5) copies of all materials to be presented for distribution to the panel members; other copies may be provided to the audience at the discretion of the participant.

(8) Statements made by members of the meeting panel are intended to facilitate discussion of the issues or to clarify issues. Any statement made during the meeting by a member of the panel is not intended to be, and should not be construed as, a position of the FAA or JAA.

(9) The meetings are designed to solicit public views and more complete information on proposed harmonization initiatives. Therefore, the meetings will be conducted in an informal and nonadversarial manner. No individual will be subject to cross-examination by any other participant; however, panel members may ask questions to clarify a statement and to ensure a complete and accurate record.

Issued in Washington, DC, on February 14, 2003.

**Florence L. Hamn,**

*Acting Manager, Aircraft and Airport Rules Division.*

[FR Doc. 03–4054 Filed 2–14–03; 1:49 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Environmental Impact Statement: Bronx County, NY

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed construction project for the Bruckner-Sheridan Expressway Interchange and for Improved Access to the Hunts Point Peninsula, in Bronx County, New York.

**FOR FURTHER INFORMATION CONTACT:** Douglas Currey, P.E., Regional Director, New York State Department of Transportation, Hunters Point Plaza 47–40 21st Street, Long Island City, New York 11101, Telephone: (718) 482–4526; or Robert Arnold, Division Administrator, Federal Highway Administration, New York Division, Leo W. O'Brien Federal Building, 7th Floor, Clinton Avenue and North Pearl Street, Albany, New York 12207, Telephone (518) 431–4127.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the New York State Department of Transportation (NYSDOT) will prepare an Environmental Impact Statement on the proposal to improve safety and traffic flow at the Bruckner Expressway (I–278) at its interchange with the Arthur V. Sheridan Expressway (I–895) as well as to improve access in and out of the Hunts Points Peninsula from the Expressway System.

The objectives of the project are:

- Effectively move people and goods in faster, safer and easier ways by improving the existing roadways, bridges, bicycle paths and pedestrian walkways. This will include improvements to the Bruckner-Sheridan Interchange and local arterials for a better access into and from the Hunts Point Peninsula.

- Reduce the number of accidents in the project area and increase pedestrian safety at busy intersections, such as at Bruckner Boulevard and Hunts Points Ave.

- Support economic development by providing easier access to and from the Hunts Point Peninsula, while eliminating the bottlenecks at the Bruckner Expressway.

- Enhance the quality of life for the residential community by reducing the volume of commercial vehicles on residential streets and easing congestion

for motorists traveling through the project area.

- Support environmental enhancements in coordination with City, State and Federal Agencies.

*Alternatives:* Various alternatives have already been identified through past studies. The findings of the past studies will be used as a starting point and will be included with new alternatives that will be developed through an extensive public scoping process. The list of alternatives and solutions will be refined throughout the scoping process as the public's comments and suggestions are taken into consideration.

Alternatives identified to date include:

*No Action*—An analysis of the current infrastructure and the likely state of the area's infrastructure, levels of congestion, *etc.* in the future without any improvements.

*Transportation Systems Management*—This would provide a strategy to make the most of the current transportation network with minimal capital investment. Emphasis will be placed on operating improvements and strategic upgrades such as the installation of various traffic control devices (*e.g.*, Directional Signs) throughout the corridor.

*Build*—These includes the long-term alternatives and are more detailed and complex:

- Reconstruction of the Bruckner-Sheridan Interchange to improve highway geometrics in the area adjacent to the Bronx River by creating flyover structures above the Bronx River. This alternative was identified in the Expanded Project Proposal and will be further investigated during the EIS Process.

• Improve Access into and out the Hunts Point Peninsula via Edgewater Road, by reconstructing the southern terminus of the Sheridan Expressway. This alternative was identified in the Expanded Project Proposal and will be further investigated during the EIS Process.

• Construction of Ramps from the Bruckner Expressway at Leggett Avenue at the Bruckner Expressway is also aimed at improved access to the Hunts Point Peninsula. This alternative was identified during past public involvement and will be expanded upon during this process.

• Construction of a road/rail improvement to Hunts Point from Port Morris along the water and rail lines to improve access in and out the Hunts Point Peninsula.

- Deconstruction of the Sheridan Expressway will be investigated as a potential element of some alternatives.

Letters describing the proposed action and soliciting comments will be sent to Federal, State and local agencies, and to private organizations and citizens who have previously expressed interest in this proposal. In addition to scoping discussion with these interested parties, the general public will have the opportunity to make scoping comments both in writing and in person at Public Information/Scoping Meetings that will be held at the Hunts Point Branch Regional Library, 877 Southern Boulevard, Bronx, NY 10459, on March 18, 2003, from 5 p.m. to 9 p.m., and at the Bronx Borough Board Briefing Room, 198 East 161st Street, 2nd Floor, Bronx, NY 10451, on March 20, 2003, from 5 p.m. to 9 p.m. After the DEIS is prepared, it will be available for public and agency review and comment. This will be followed by a public hearing. Public notice will be given of the time and place of the hearing.

To ensure that the full range of issues related to this proposed action area addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action should be directed to the NYSDOT and FHWA at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

**Authority:** 23 U.S.C. 315; 23 CFR 771.123.

Issued on: February 12, 2003.

**David M. Hart,**

*Senior Operations Engineer, Federal Highway Administration, Albany, NY.*

[FR Doc. 03-4029 Filed 2-19-03; 8:45 am]

**BILLING CODE 4910-22-M**

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

February 5, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the

OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before March 24, 2003 to be assured of consideration.

### U.S. Customs Service (CUS)

*OMB Number:* 1515-0032.

*Form Number:* Customs Form 5125.

*Type of Review:* Extension.

*Title:* Application for Withdrawal of Bonded Stores for Fishing Vessels and Certification of Use.

*Description:* The Customs Form 5125 is used for the withdrawal and lading of bonded merchandise (especially alcoholic beverages) for use on board fishing vessels and foreign or domestic vessels involved in international trade. The form also certifies the use: total consumption or partial consumption with secure storage for use of next voyage.

*Respondents:* Business or other for-profit, Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 500.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 5 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/*

*Recordkeeping Burden:* 42 hours.

*OMB Number:* 1515-0050.

*Form Number:* Customs Forms 3347 and 3347-A.

*Type of Review:* Extension.

*Title:* **CUSTOMS FORM 3347:** Declaration of Owner Merchandise Obtained in Pursuance of Purchase; and **CUSTOMS FORM 3347-A:** Declaration of Importer of Record When Entry is Made by an Agent.

*Description:* Customs Forms 3347 and 3347-A allow an agent to submit, subsequent to making the entry, the declaration of the importer of record which is required by statute. These forms also permit a nominal importer of record to file the declaration of the actual owner.

*Respondents:* Business or other for-profit, Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 5,700.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 6 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/*

*Recordkeeping Burden:* 570 hours.

*OMB Number:* 1515-0108.

*Form Number:* None.

*Type of Review:* Extension.

*Title:* Declaration of a Person Abroad Who Receives and is Returning Merchandise to the U.S.

*Description:* The declaration is used under conditions where articles are



imported and then exported and then reimported free of duty due to the declaration, it is used to ensure Customs control over duty-free merchandise.

*Respondents:* Individuals or households, Business or other for-profit.

*Estimated Number of Respondents/Recordkeepers:* 500.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 10 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/Recordkeeping Burden:* 250 hours.

*OMB Number:* 1515-0142.

*Form Number:* None.

*Type of Review:* Extension.

*Title:* Transfer of Cargo to a Container Station.

*Description:* The container station operator may file an application for transfer of a container intact to a container station which is moved from the place of unloading or from a bonded carrier after transportation in-bond before filing of the entry for the purpose of breaking bulk and redelivery.

*Respondents:* Business or other for-profit, Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 380.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 7 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/Recordkeeping Burden:* 2,513 hours.

*OMB Number:* 1515-0173.

*Form Number:* None.

*Type of Review:* Extension.

*Title:* Blanket Certification of Chemical Substances.

*Description:* The Customs Regulations require an importer's certification in connection with the importation of chemical substances subject to the Toxic Substances Control Act. This collection reduces the regulatory burden by permitting use of a blanket certification for multiple shipments in lieu of a separate certification for each individual shipment.

*Respondents:* Business or other for-profit, Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 300.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 15 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/Recordkeeping Burden:* 75 hours.

*OMB Number:* 1515-0222.

*Form Number:* None.

*Type of Review:* Extension.

*Title:* Bond Procedures for Articles Subject to Exclusion Orders Issued by the U.S. International Trade Commission.

*Description:* This collection of information is required to ensure compliance with section 337 of the

Tariff Act of 1930, regarding bond procedures for the entry of articles subject to exclusion orders by the International Trade Commission.

*Respondents:* Business or other for-profit, Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 50.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 30 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting/Recordkeeping Burden:* 50 hours.

*Clearance Officer:* Tracey Denning (202) 927-1429, U.S. Customs Service, Information Services Branch, Ronald Reagan Building, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229.

*OMB Reviewer:* Joseph F. Lackey, Jr. (202) 395-7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Treasury PRA, Clearance Officer.*

[FR Doc. 03-4034 Filed 2-19-03; 8:45 am]

**BILLING CODE 4820-02-P**

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

February 5, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before March 24, 2003 to be assured of consideration.

### Financial Crimes Enforcement Network (FinCEN)

*OMB Number:* 1506-0005.

*Form Number:* FinCEN 103 (IRS Form 8362).

*Type of Review:* Revision.

*Title:* Currency Transaction Reports by Casinos.

*Description:* Casinos file Form 103 for currency transactions in excess of \$10,000 a day pursuant to 31 U.S.C. 5313(a) and 31 CFR 103.22(a)(2). The form is used by criminal investigators,

and taxation and regulatory enforcement authorities, during the course of investigations involving financial crimes.

*Respondents:* Business or other for-profit, Federal Government.

*Estimated Number of Respondents/Recordkeepers:* 550.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 24 minutes.

*Estimated Total Reporting/Recordkeeping Burden:* 79,200 hours.

*Clearance Officer:* Steve Rudzinski (703) 905-3845, Financial Crimes Enforcement Network, 2070 Chain Bridge Road, Suite 200, Vienna, VA 22182.

*OMB Reviewer:* Joseph F. Lackey, Jr. (202) 395-7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports, Management Officer.*

[FR Doc. 03-4035 Filed 2-19-03; 8:45 am]

**BILLING CODE 4810-02-P**

## DEPARTMENT OF THE TREASURY

### Customs Service

### Extension of and Changes to the General Program Test Regarding Post Entry Amendment Processing

**AGENCY:** Customs Service, Treasury.

**ACTION:** General notice.

**SUMMARY:** This document announces that the general program test regarding post entry amendment processing is being extended for a one year period. The document also announces minor modifications to the test: a database enhancement that permits participants to use any Microsoft Word software to interface with Customs database and a change of the location to where quarterly reports should be mailed. Also, the document announces that the database program name has changed to "Post Summary Adjustment." Except for these changes, the test will continue to operate in accordance with the notice published in the **Federal Register** on November 28, 2000.

**DATES:** The test allowing post entry amendment to entry summaries is extended to December 31, 2003.

**FOR FURTHER INFORMATION CONTACT:** Debbie Scott (202/927-1962) or Don Yando (Chief; 202/927-1082), Entry and Drawback Management Branch, Office of Field Operations.

**SUPPLEMENTARY INFORMATION:**



**Background**

Customs announced and explained the post entry amendment processing test in a general notice document published in the **Federal Register** (65 FR 70872) on November 28, 2000. That notice announced that the test would commence no earlier than December 28, 2000, and run for approximately one year. On January 7, 2002, Customs published a general notice in the **Federal Register** (67 FR 768) extending the test for a one year period to December 31, 2002.

The test allows importers to amend entry summaries (not informal entries) prior to liquidation by filing with Customs either an individual amendment letter upon discovery of an error or a quarterly tracking report covering any errors that occurred during the quarter. The November 28, 2000, general notice explained how to file post entry amendments for revenue related errors and non-revenue related errors and the consequences of

misconduct by importers during the test. It also provided that there are no application procedures or eligibility requirements.

This document announces that the test is being extended to December 31, 2003. To participate in the test, an importer need only follow the procedure for making a post entry amendment set forth in the November 28, 2000, general notice.

In addition, based on comments received in response to the November 28, 2000, general notice and Customs evaluation of the program, Customs is making two changes to the test. The first pertains to the kind of software that is required to participate in the test. Up to now, a test participant needed Microsoft Word 97 or 98 to interface with the program database. Now, due to an enhancement of the database, a participant may use any Microsoft Word software to interface with the database.

The second change pertains to the mailing of quarterly reports to Customs. Up to now, quarterly reports were

mailed to Customs Headquarters. Now, these reports must be mailed to the port director of the port of entry handling the entry summaries involved.

Both of these changes are effective upon publication of this document in the **Federal Register**.

Finally, Customs notes that the name for the test under the database has been changed from "Post Entry Amendment" to "Post Summary Adjustment." The test program itself will continue to be known as the "Post Entry Amendment" (or PEA) test program. Customs also notes that the test may be further extended if warranted. Additional information on the post entry amendment procedure can be found under "Importing and Exporting" at <http://www.customs.gov>.

Dated: February 12, 2003

**Jayson P. Ahern,**

*Assistant Commissioner; Office of Field Operations.*

[FR Doc. 03-4078 Filed 2-19-03; 8:45 am]

**BILLING CODE 4820-02-P**

# Corrections

Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## CONSUMER PRODUCT SAFETY COMMISSION

### Petition HP 01–3 Requesting a Ban of Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment

#### *Correction*

In notice document 03–3824 beginning on page 7510 in the issue of Friday, February 14, 2003, make the following corrections:

1. On page 7510, in the second column, under the **SUMMARY** heading, in the first paragraph, in the fourth line, “CPCS” should read, “CPSC”.

2. On the same page, under the same heading, in the same paragraph, in the eighth line, “CPSE” should read, “CPSC”.

3. On the same page, in the third column, under the **ADDRESSES** heading, in the sixth line, “*spsc-os@cpsc.gov*” should read, “*cpsc-os@cpsc.gov*”.

[FR Doc. C3–3824 Filed 2–19–03; 8:45 am]

BILLING CODE 1505–01–D

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco, and Firearms

#### 27 CFR Part 55

[Notice No. 968]

RIN 1512–AB48

### Commerce in Explosives (2000R–9P)

#### *Correction*

In proposed rule document 03–1946 beginning on page 4406 in the issue of Wednesday, January 29, 2003 make the following correction:

#### § 55.208 [Corrected]

On page 4420, in §55.208, in the first column, in paragraph (a)(2)(i), in the fourth line, “January 29, 2004” should read “[Insert Date 1 Year After the Date of Publication of the Final Rule in the Federal Register]”.

[FR Doc. C3–1946 Filed 2–19–03; 8:45 am]

BILLING CODE 1505–01–D



# Federal Register

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**Thursday,  
February 20, 2003**

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## **Part II**

### **Department of Health and Human Services**

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**Office of the Secretary**

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**45 CFR Parts 160, 162, and 164  
Health Insurance Reform: Security  
Standards; Final Rule**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Parts 160, 162, and 164

[CMS-0049-F]

RIN 0938-AI57

### Health Insurance Reform: Security Standards

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. The use of the security standards will improve the Medicare and Medicaid programs, and other Federal health programs and private health programs, and the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information. This final rule implements some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**DATES:** *Effective Date:* These regulations are effective on April 21, 2003.

*Compliance Date:* Covered entities, with the exception of small health plans, must comply with the requirements of this final rule by April 21, 2005. Small health plans must comply with the requirements of this final rule by April 21, 2006.

**FOR FURTHER INFORMATION CONTACT:** William Schooler, (410) 786-0089.

#### SUPPLEMENTARY INFORMATION:

#### Availability of Copies and Electronic Access

To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at

many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO access, a service of the U.S. Government Printing Office. The Web site address is <http://www.access.gpo.gov/nara/index.html>.

#### I. Background

The Department of Health and Human Services (HHS) Medicare Program, other Federal agencies operating health plans or providing health care, State Medicaid agencies, private health plans, health care providers, and health care clearinghouses must assure their customers (for example, patients, insured individuals, providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected. The confidentiality of health information is threatened not only by the risk of improper access to stored information, but also by the risk of interception during electronic transmission of the information. The purpose of this final rule is to adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. Currently, no standard measures exist in the health care industry that address all aspects of the security of electronic health information while it is being stored or during the exchange of that information between entities.

This final rule adopts standards as required under title II, subtitle F, sections 261 through 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191. These standards require measures to be taken to secure this information while in the custody of entities covered by HIPAA (covered entities) as well as in transit between covered entities and from covered entities to others.

The Congress included provisions to address the need for safeguarding electronic health information and other administrative simplification issues in HIPAA. In subtitle F of title II of that law, the Congress added to title XI of the Social Security Act a new part C, entitled "Administrative Simplification" (hereafter, we refer to the Social Security Act as "the Act"; we refer to the other laws cited in this document by their names). The purpose of subtitle F is to improve the Medicare program under title XVIII of the Act, the Medicaid program under title XIX of the Act, and the efficiency and effectiveness

of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information.

Part C of title XI consists of sections 1171 through 1179 of the Act. These sections define various terms and impose requirements on HHS, health plans, health care clearinghouses, and certain health care providers. These statutory sections are discussed in the Transactions Rule, at 65 FR 50312, on pages 50312 through 50313, and in the final rules adopting Standards for Privacy of Individually Identifiable Health Information, published on December 28, 2000 at 65 FR 82462 (Privacy Rules), on pages 82470 through 82471, and on August 14, 2002 at 67 FR 53182. The reader is referred to those discussions.

Section 1173(d) of the Act requires the Secretary of HHS to adopt security standards that take into account the technical capabilities of record systems used to maintain health information, the costs of security measures, the need to train persons who have access to health information, the value of audit trails in computerized record systems, and the needs and capabilities of small health care providers and rural health care providers. Section 1173(d) of the Act also requires that the standards ensure that a health care clearinghouse, if part of a larger organization, has policies and security procedures that isolate the activities of the clearinghouse with respect to processing information so as to prevent unauthorized access to health information by the larger organization. Section 1173(d) of the Act provides that covered entities that maintain or transmit health information are required to maintain reasonable and appropriate administrative, physical, and technical safeguards to ensure the integrity and confidentiality of the information and to protect against any reasonably anticipated threats or hazards to the security or integrity of the information and unauthorized use or disclosure of the information. These safeguards must also otherwise ensure compliance with the statute by the officers and employees of the covered entities.

#### II. General Overview of the Provisions of the Proposed Rule

On August 12, 1998, we published a proposed rule (63 FR 43242) to establish a minimum standard for security of electronic health information. We proposed that the standard would require the safeguarding of all electronic health information by covered entities. The proposed rule also proposed a

standard for electronic signatures. This final rule adopts only security standards. All comments concerning the proposed electronic signature standard, responses to these comments, and a final rule for electronic signatures will be published at a later date. A detailed discussion of the provisions of the August 12, 1998 proposed rule can be found at 63 FR 43245 through 43259.

We originally proposed to add part 142, entitled "Administrative Requirements," to title 45 of the Code of Federal Regulations (CFR). It has now been determined that this material will reside in subchapter C of title 45, consisting of parts 160, 162, and 164. Subpart A of part 160 contains the general provisions applicable to all the Administrative Simplification rules; other subparts of part 160 will contain other requirements applicable to all standards. Part 162 contains the standards for transactions and code sets and will contain the identifier standards. Part 164 contains the standards relating to privacy and security. Subpart A of part 164 contains general provisions applicable to part 164; subpart E contains the privacy standards. Subpart C of part 164, which is adopted in this final rule, adopts standards for the security of electronic protected health information.

### III. Analysis of, and Responses to, Public Comments on the Proposed Rule

We received approximately 2,350 timely public comments on the August 12, 1998 proposed rule. The comments came from professional associations and societies, health care workers, law firms, health insurers, hospitals, and private individuals. We reviewed each commenter's letter and grouped related comments. Some comments were identical. After associating like comments, we placed them in categories based on subject matter or based on the section(s) of the regulations affected and then reviewed the comments.

In this section of the preamble, we summarize the provisions of the proposed regulations, summarize the related provisions in this final rule, and respond to comments received concerning each area.

It should be noted that the proposed Security Rule contained multiple proposed "requirements" and "implementation features." In this final rule, we replace the term "requirement" with "standard." We also replace the phrase "implementation feature" with "implementation specification." We do this to maintain consistency with the use of those terms as they appear in the statute, the Transactions Rule, and the Privacy Rule. Within the comment and

response portion of this final rule, for purposes of continuity, however, we use "requirement" and "implementation feature" when we are referring specifically to matters from the proposed rule. In all other instances, we use "standard" and "implementation specification."

The proposed rule would require that each covered entity (as now described in § 160.102) engaged in the electronic maintenance or transmission of health information pertaining to individuals assess potential risks and vulnerabilities to such information in its possession in electronic form, and develop, implement, and maintain appropriate security measures to protect that information. Importantly, these measures would be required to be documented and kept current.

The proposed security standard was based on three basic concepts that were derived from the Administrative Simplification provisions of HIPAA. First, the standard should be comprehensive and coordinated to address all aspects of security. Second, it should be scalable, so that it can be effectively implemented by covered entities of all types and sizes. Third, it should not be linked to specific technologies, allowing covered entities to make use of future technology advancements.

The proposed standard consisted of four categories of requirements that a covered entity would have to address in order to safeguard the integrity, confidentiality, and availability of its electronic health information pertaining to individuals: administrative procedures, physical safeguards, technical security services, and technical mechanisms. The implementation features described the requirements in greater detail when that detail was needed. Within the four categories, the requirements and implementation features were presented in alphabetical order to convey that no one item was considered to be more important than another.

The four proposed categories of requirements and implementation features were depicted in tabular form along with the electronic signature standard in a combined matrix located at Addendum 1. We also provided a glossary of terms, at Addendum 2, to facilitate a common understanding of the matrix entries, and at Addendum 3, we mapped available existing industry standards and guidelines to the proposed security requirements.

#### A. General Issues

The comment process overwhelmingly validated our basic

assumptions that the entities affected by this regulation are so varied in terms of installed technology, size, resources, and relative risk, that it would be impossible to dictate a specific solution or set of solutions that would be useable by all covered entities. Many commenters also supported the concept of technological neutrality, which would afford them the flexibility to select appropriate technology solutions and to adopt new technology over time.

#### 1. Security Rule and Privacy Rule Distinctions

As many commenters recognized, security and privacy are inextricably linked. The protection of the privacy of information depends in large part on the existence of security measures to protect that information. It is important that we note several distinct differences between the Privacy Rule and the Security Rule.

The security standards below define administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The standards require covered entities to implement basic safeguards to protect electronic protected health information from unauthorized access, alteration, deletion, and transmission. The Privacy Rule, by contrast, sets standards for how protected health information should be controlled by setting forth what uses and disclosures are authorized or required and what rights patients have with respect to their health information.

As is discussed more fully below, this rule narrows the scope of the information to which the safeguards must be applied from that proposed in the proposed rule, electronic health information pertaining to individuals, to protected health information in electronic form. Thus, the scope of information covered in this rule is consistent with the Privacy Rule, which addresses privacy protections for "protected health information." However, the scope of the Security Rule is more limited than that of the Privacy Rule. The Privacy Rule applies to protected health information in any form, whereas this rule applies only to protected health information in electronic form. It is true that, under section 1173(d) of the Act, the Secretary has authority to cover "health information," which, by statute, includes information in other than electronic form. However, because the proposed rule proposed to cover only health information in electronic form, we do not include security standards for health information in non-electronic form in this final rule.

We received a number of comments that pertained to privacy issues. These issues were considered in the development of the Privacy Rule and many of these comments were addressed in the preamble of the Privacy Rule. Therefore, we are referring the reader to that document for a discussion of those issues.

## 2. Level of Detail

We solicited comments as to the level of detail expressed in the required implementation features; that is, we specifically wanted to know whether commenters believe the level of detail of any proposed requirement went beyond what is necessary or appropriate. We received numerous comments expressing the view that the security standards should not be overly prescriptive because the speed with which technology is evolving could make specific requirements obsolete and might in fact deter technological progress. We have accordingly written the final rule to frame the standards in terms that are as generic as possible and which, generally speaking, may be met through various approaches or technologies.

## 3. Implementation Specifications

In addition to adopting standards, this rule adopts implementation specifications that provide instructions for implementing those standards.

However, in some cases, the standard itself includes all the necessary instructions for implementation. In these instances, there may be no corresponding implementation specification for the standard specifically set forth in the regulations text. In those instances, the standards themselves also serve as the implementation specification. In other words, in those instances, we are adopting one set of instructions as both the standard and the implementation specification. The implementation specification would, accordingly, in those instances be required.

In this final rule, we adopt both "required" and "addressable" implementation specifications. We introduce the concept of "addressable implementation specifications" to provide covered entities additional flexibility with respect to compliance with the security standards.

In meeting standards that contain addressable implementation specifications, a covered entity will ultimately do one of the following: (a) Implement one or more of the addressable implementation specifications; (b) implement one or more alternative security measures; (c)

implement a combination of both; or (d) not implement either an addressable implementation specification or an alternative security measure. In all cases, the covered entity must meet the standards, as explained below.

The entity must decide whether a given addressable implementation specification is a reasonable and appropriate security measure to apply within its particular security framework. This decision will depend on a variety of factors, such as, among others, the entity's risk analysis, risk mitigation strategy, what security measures are already in place, and the cost of implementation. Based upon this decision the following applies:

(a) If a given addressable implementation specification is determined to be reasonable and appropriate, the covered entity must implement it.

(b) If a given addressable implementation specification is determined to be an inappropriate and/or unreasonable security measure for the covered entity, but the standard cannot be met without implementation of an additional security safeguard, the covered entity may implement an alternate measure that accomplishes the same end as the addressable implementation specification. An entity that meets a given standard through alternative measures must document the decision not to implement the addressable implementation specification, the rationale behind that decision, and the alternative safeguard implemented to meet the standard. For example, the addressable implementation specification for the integrity standard calls for electronic mechanisms to corroborate that data have not been altered or destroyed in an unauthorized manner (see 45 CFR 164.312(c)(2)). In a small provider's office environment, it might well be unreasonable and inappropriate to make electronic copies of the data in question. Rather, it might well be more practical and afford a sufficient safeguard to make paper copies of the data.

(c) A covered entity may also decide that a given implementation specification is simply not applicable (that is, neither reasonable nor appropriate) to its situation and that the standard can be met without implementation of an alternative measure in place of the addressable implementation specification. In this scenario, the covered entity must document the decision not to implement the addressable specification, the rationale behind that decision, and how the standard is being met. For example, under the

information access management standard, an access establishment and modification implementation specification reads: "implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process" (45 CFR 164.308(a)(4)(ii)(c)). It is possible that a small practice, with one or more individuals equally responsible for establishing and maintaining all automated patient records, will not need to establish policies and procedures for granting access to that electronic protected health information because the access rights are equal for all of the individuals.

a. *Comment:* A large number of commenters indicated that mandating 69 implementation features would result in a regulation that is too burdensome, intrusive, and difficult to implement. These commenters requested that the implementation features be made optional to meet the requirements. A number of other commenters requested that all implementation features be removed from the regulation.

*Response:* Deleting the implementation specifications would result in the standards being too general to understand, apply effectively, and enforce consistently. Moreover, a number of implementation specifications are so basic that no covered entity could effectively protect electronic protected health information without implementing them. We selected 13 of these mandatory implementation specifications based on (1) the expertise of Federal security experts and generally accepted industry practices and, (2) the recommendation for immediate implementation of certain technical and organizational practices and procedures described in Chapter 6 of *For The Record: Protecting Electronic Health Information*, a 1997 report by the National Research Council (NRC). These mandatory implementation specifications are referred to as required implementation specifications and are reflected in the NRC report's recommendations. Risk Analysis and Risk management are found in the NRC recommendation title System Assessment; Sanction Policy is required in the Sanctions recommendation; Information system Activity Review is discussed in Audit Trails; Response and Reporting circumstances.

In addition, a number of voluntary national and regional organizations have been formed to address HIPAA implementation issues and to facilitate

communication among trading partners. These include the Strategic National Implementation Process (SNIP) developed under the auspices of the Workgroup for Electronic Data Interchange (WEDI), an organization named in the HIPAA statute to consult with the Secretary of HHS on HIPAA issues. Some of these organizations have developed white papers, tools, and recommended best practices addressing a number of HIPAA issues, including security. Covered entities may wish to examine these products to determine if they are relevant and useful in their own implementation efforts. A partial list of these organizations can be found at <http://www.wedi/snip.org>. We believe that these and other future industry-developed guidelines and/or models may provide valuable assistance to covered entities implementing these standards but must caution that HHS does not rate or endorse any such guidelines and/or models and the value of its content must be determined by the user.

b. *Comment:* Many commenters asked us to develop guidelines and models to aid in complying with the Security Rule. Several commenters either offered to participate in the development of guidelines and models or suggested entities that should be invited to participate.

*Response:* We agree that creation of compliance tools and guidelines for different business environments could assist covered entities to implement the HIPAA Security Rule. We plan to issue guidance documents after the publication of this final rule. However, it is critical for each covered entity to establish policies and procedures that address its own unique risks and circumstances.

In addition, a number of voluntary national and regional organizations have been formed to address HIPAA implementation issues and to facilitate communication among trading partners. These include the Strategic National Implementation Process (SNIP) developed under the auspices of the Workgroup for Electronic Data Interchange (WEDI), an organization named in the HIPAA statute to consult with the Secretary of HHS on HIPAA issues. Some of these organizations have developed white papers, tools, and recommended best practices addressing a number of HIPAA issues, including security.

Covered entities may wish to examine these products to determine if they are relevant and useful in their own implementation efforts. A partial list of these organizations can be found at <http://www.snip.wedi.org>. We believe

that these and other future industry-developed guidelines and/or models may provide valuable assistance to covered entities implementing these standards but must caution that HHS does not rate or endorse any such guidelines and/or models and the value of its content must be determined by the user.

#### 4. Examples

*Comment:* We received a number of comments that demonstrated confusion regarding the purpose of the examples of security solutions that were included throughout the proposed rule. Commenters stated that they could not, or did not wish to, adopt various security measures suggested in examples. Other commenters asked that we include additional options within the examples. Some commenters referred specifically to the example provided in the proposed rule demonstrating how a small or rural provider might comply with the standards. One commenter asked for clarification that the examples are not mandatory measures that are required to demonstrate compliance, but are merely meant as a guide when implementing the security standards. Another commenter expressed support for the use of examples to clarify the intent of text descriptions.

*Response:* We wish to clarify that examples are used only as illustrations of possible approaches, and are included to serve as a springboard for ideas. The steps that a covered entity will actually need to take to comply with these regulations will be dependent upon its own particular environment and circumstances and risk assessment. The examples do not describe mandatory measures, nor do they represent the only, or even the best, way of achieving compliance. The most appropriate means of compliance for any covered entity can only be determined by that entity assessing its own risks and deciding upon the measures that would best mitigate those risks.

#### B. Applicability (§ 164.302)

We proposed that the security standards would apply to health plans, health care clearinghouses, and to health care providers that maintain or transmit health information electronically. The proposed security standards would apply to all electronic health information maintained or transmitted, regardless of format (standard transaction or a proprietary format). No distinction would be made between internal corporate entity communication or communication

external to the corporate entity. Electronic transmissions would include transactions using all media, even when the information is physically moved from one location to another using magnetic tape, disk, or other machine readable media. Transmissions over the Internet (wide-open), extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, and private networks would be included. We proposed that telephone voice response and “faxback” systems (a request for information made via voice using a fax machine and requested information returned via that same machine as a fax) would not be included but we solicited comments on this proposed exclusion.

This final rule simplifies the applicability statement greatly. Section 164.302 provides that the security standards apply to covered entities; the scope of the information covered is specified in § 164.306 (see the discussion under that section below regarding the changes and revisions to the scope of information covered).

1. *Comment:* A number of commenters requested clarification of who must comply with the standards. The preamble and proposed § 142.102 and § 142.302 stated: “Each person described in section 1172(a) of the Act who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards.” Commenters suggested that this statement is in conflict with the law, which defines a covered entity as a health plan, a clearinghouse, or a health care provider that conducts certain transactions electronically. The commenters apparently did not realize that section 1172(a) of the Act contains the definition of covered entities.

*Response:* Section 164.302 below makes the security standards applicable to “covered entities.” The term “covered entity” is defined at § 160.103 as one of the following: (1) A health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by part 162 of title 45 of the Code of Federal Regulations (CFR). The rationale for the use and the meaning of the term “covered entity” is discussed in the preamble to the Privacy Rule (65 FR 82476 through 82477).

As that discussion makes clear, the standards only apply to health care providers who engage electronically in the transactions for which standards have been adopted.

2. *Comment:* Several commenters recommended expansion of applicability, either to other specific entities, or to all entities involved in health care. Others wanted to know whether the standards apply to entities such as employers, public health organizations, medical schools, universities, research organizations, plan brokers, or non-EDI providers. One commenter asked whether the standards apply to State data organizations operating in capacities other than as plans, clearinghouses, or providers. Still other commenters stated that it was inappropriate to include physicians and other health care professionals in the same category as plans and clearinghouses, arguing that providers should be subject to different, less burdensome requirements because they already protect health information.

*Response:* The statute does not cover all health care entities that transmit or maintain individually identifiable health information. Section 1172(a) of the Act provides that only health plans, health care clearinghouses, and certain health care providers (as discussed above) are covered. With respect to the comments regarding the difference between providers and plans/clearinghouses, we have structured the Security Rule to be scalable and flexible enough to allow different entities to implement the standards in a manner that is appropriate for their circumstances. Regarding the coverage of entities not within the jurisdiction of HIPAA, see the Privacy Rule at 82567 through 82571.

3. *Comment:* One commenter asked whether the standards would apply to research organizations, both to those affiliated with health care providers and those that are not.

*Response:* Only health plans, health care clearinghouses, and certain health care providers are required to comply with the security standards. Researchers who are members of a covered entity's work force may be covered by the security standards as part of the covered entity. See the definition of "workforce" at 45 CFR 160.103. Note, however, that a covered entity could, under appropriate circumstances, exclude a researcher or research division from its health care component or components (see § 164.105(a)). Researchers who are not part of the covered entity's workforce and are not themselves covered entities are not subject to the standards.

4. *Comment:* Several commenters stated that internal networks and external networks should be treated differently. One commenter asked for further clarification of the difference

between what needs to be secured external to a corporation versus the security of data movement within an organization. Another stated that complying with the security standards for internal communications may prove difficult and costly to monitor and control. In contrast, one commenter stated that the existence of requirements should not depend on whether use of information is for internal or external purposes.

Another commenter argued that the regulation goes beyond the intent of the law, and while communication of electronic information between entities should be covered, the law was never intended to mandate changes to an entity's internal automated systems. One commenter requested that raw data that are only for the internal use of a facility be excluded, provided that reasonable safeguards are in place to keep the raw data under the control of the facility.

*Response:* Section 1173(d)(2) of the Act states: Each person described in section 1172(a) who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards—(A) to ensure the integrity and confidentiality of the information; (B) to protect against any reasonably anticipated—(i) threats or hazards to the security or integrity of the information; and (ii) unauthorized uses or disclosures of the information; and (C) otherwise to ensure compliance with this part by the officers and employees of such person.

This language draws no distinction between internal and external data movement. Therefore, this final rule covers electronic protected health information at rest (that is, in storage) as well as during transmission.

Appropriate protections must be applied, regardless of whether the data are at rest or being transmitted. However, because each entity's security needs are unique, the specific protections determined appropriate to adequately protect information will vary and will be determined by each entity in complying with the standards (see the discussion below).

5. *Comment:* Several commenters found the following statement in the proposed rule (63 FR 43245) at section II.A. confusing and asked for clarification: "With the exception of the security standard, transmission within a corporate entity would not be required to comply with the standards."

*Response:* In the final Transactions Rule, we revised our approach concerning the transaction and code set exemptions, replacing this concept with

other tests that determine whether a particular transaction is subject to those standards (see the discussion in the Transactions Rule at 65 FR 50316 through 50318). We also note that the Privacy Rule regulates a covered entity's use, as well as disclosure, of protected health information.

6. *Comment:* One commenter stated that research would be hampered if proposed § 142.306(a) applied. The commenter believes that research uses of health information should be excluded or the standard should be revised to allow appropriate flexibility for research depending on the risk to patients or subjects (for example, if the information is anonymous, there is no risk, and it would not be necessary to meet the security standards).

*Response:* If electronic protected health information is de-identified (as truly anonymous information would be), it is not covered by this rule because it is no longer electronic protected health information (see 45 CFR 164.502(d) and 164.514(a)). Electronic protected health information received, created, or maintained by a covered entity, or that is transmitted by covered entities, is covered by the security standards and must be protected. To the extent a researcher is a covered entity, the researcher must comply with these standards with respect to electronic protected health information. Otherwise, the conditions for release of such information to researchers is governed by the Privacy Rule. See, for example, 45 CFR 164.512(i), 164.514(e) and 164.502(d). These standards would not apply to the researchers as such in the latter circumstances.

7. *Comment:* One commenter asked to what extent individual patients are subject to the standards. For example, some telemedicine practices support the use of diagnostic systems in the patient's home, which can be used to conduct tests and send results to a remote physician. In other cases, patients may be responsible for the filing of insurance claims directly and will need the ability to verify facts, confirm receipt of claims, and so on. The commenter asked if it is the intent of the rule to include electronic transmission to or from the patient.

*Response:* Patients are not covered entities and, thus, are not subject to these standards. With respect to transmissions from covered entities, covered entities must protect electronic protected health information when they transmit that information. See also the discussion of encryption in section III.G.



### C. Transition to the Final Rule

The proposed rule included definitions for a number of terms that have now already been promulgated as part of the Transactions Rule or the Privacy Rule. Comments related to the definitions of “code set,” “health care clearinghouse,” “health plan,” “health care provider,” “small health plan,” “standard” and “transaction,” are addressed in the Transactions Rule at 65 FR 50319 through 50320. Comments concerning the definition of “individually identifiable health information” are discussed below, but are also addressed in the Privacy Rule at 65 FR 82611 through 82613. In addition, a few terms were redefined in the final Standards for Privacy of Individually Identifiable Health Information (67 FR 53182), issued on August 14, 2002 (Privacy Modifications). Certain terms that were defined in the proposed rule are not used in the final rule because they are no longer necessary. Other terms defined in the proposed rule are defined within the explanation of the standards in the final rule and are discussed in the preamble discussions in § 164.308 through § 164.312.

Definitions of terms relevant to the security standards now appear in the regulations text provisions as indicated below:

§ 160.103: Definitions of the following terms relevant to this rule appear in § 160.103: “business associate,” “covered entity,” “disclosure,” “electronic media,” “electronic protected health information,” “health care,” “health care clearinghouse,” “health care provider,” “health information,” “health plan,” “individual,” “individually identifiable health information,” “implementation specification,” “organized health care arrangement,” “protected health information,” “standard,” “use,” and “workforce.” These terms were discussed in connection with the Transaction and Privacy Rules and with the exception of the terms “covered entity,” “disclosure,” “electronic protected health information,” “health information,” “individual,” “organized health care arrangement,” “protected health information,” and “use,” we will not discuss them in this document. We note that the definition of those terms are not changed in the final rule.

§ 162.103: We have moved the definition of “electronic media” at § 162.103 to § 160.103 and have modified it to clarify that the term includes storage of information. The term “electronic media” is used in the definition of “protected health

information.” Both the privacy and security standards apply to information “at rest” as well as to information being transmitted.

We note that we have deleted the reference to § 162.103 in paragraph (1)(ii) of the definition of “protected health information,” since both definitions, “electronic media” and “protected health information,” have been moved to this section. Also, it is unnecessary, because the definitions of § 160.103 apply to all of the rule in parts 160, 162, and 164.

We have also clarified that the physical movement of electronic media from place to place is not limited to magnetic tape, disk, or compact disk. This clarification removes a restriction as to what is considered to be physical electronic media, thereby allowing for future technological innovation. We further clarified that transmission of information not in electronic form before the transmission, for example, paper or voice, is not covered by this definition.

§ 164.103: The following term “plan sponsor” now appears in the new § 164.103, which consists of definitions of terms common to both subpart C and subpart E (the privacy standards). This definition was moved, without substantive change, from § 164.501 and has the meaning given to it in that section, and comments relating to this definition are discussed in connection with that section in the Privacy Rule at 65 FR 82607, 82611 through 82613, 82618 through 82622, and 82629.

§ 164.304: Definitions specifically applicable to the Security Rule appear in § 164.304, and these are discussed below. These definitions are from, or derived from, currently accepted definitions in industry publications, such as, the International Organization for Standards (ISO) 7498–2 and the American Society for Testing and Materials (ASTM) E1762–95.

The following terms in § 164.304 are taken from the proposed rule text or the glossary in Addendum 2 of the proposed rule (63 FR 43271), were not commented on, and/or are unchanged or have only minor technical changes for purposes of clarification and are not discussed below: “access,” “authentication,” “availability,” “confidentiality,” “encryption,” “password,” and “security.”

§ 164.314: Four terms were defined in § 164.504(a) of the Privacy Rule (“common control,” “common ownership,” “health care component,” and “hybrid entity”). Because these terms apply to both security and privacy, their definitions have been moved to § 164.103 without change.

Those terms are discussed in the Privacy Rule at 65 FR 82502 through 82503 and at 67 FR 53203 through 53207.

#### 1. Covered Entity (§ 160.103)

*Comment:* One commenter asked if transcription services were covered entities. The question arose because transcription is often the first electronic or printed source of clinical information. Concern was expressed about the application of physical safeguard standards to the transcribers working for transcription companies or health care providers, either as employees or as independent contractors.

Another commenter expressed concern that scalability was limited to only small providers. The commenter explained that Third Party Administrators (TPAs) allow claim processors to work at home. Some TPAs have noted that it would be impossible to comply with the security standards for home-based claims processors.

*Response:* A covered entity’s responsibility to implement security standards extends to the members of its workforce, whether they work at home or on-site. Because a covered entity is responsible for ensuring the security of the information in its care, the covered entity must include “at home” functions in its security process. While an independent transcription company or a TPA may not be covered entities, they will be a business associate of the covered entity because their activities fall under paragraph (1)(i)(a) of the definition of that term. For business associate provisions see proposed preamble section III.E.8. and § 164.308(b)(1) and § 164.314(c) of this final rule.

#### 2. Health Care and Medical Care (§ 160.103)

*Comment:* One commenter asked whether “medical care,” which is defined in the proposed rule, and “health care,” which is not, are synonymous.

*Response:* The term “medical care,” as used in the proposed rule (63 FR 43242), was intended to be synonymous with “health care.” The term “medical care” is not included in this final rule. It is, however, included in the definition of “health plan,” where its meaning is not synonymous with “health care.” For a full discussion of this issue and its resolution, see the Privacy Rule (65 FR 82578).

### 3. Health Information and Individually Identifiable Health Information 160.103)

We note that the definitions of “health information” and “individually identifiable health information” remain unchanged from those published in the Transactions and Privacy Rules.

a. *Comment:* A number of commenters asked that the definition of “health information” be expanded to include information collected by additional entities. Several commenters wanted the definition to include health information collected, maintained, or transmitted by any entity, and one commenter suggested the inclusion of aggregated information not identifiable to an individual. Several commenters asked that eligibility information be excluded from the definition of information. Several commenters wanted the definition broadened to include demographics.

*Response:* Our definition of health information is taken from the definition in section 1171(4) of the Act, which provides that health information relates to the health or condition of an individual, the provision of health care to an individual, or payment for the provision of health care to an individual. The statutory definition also specifies the entities by which health information is created or received. We note that, because “individually identifiable health information” is a subset of “health information” and by statute includes demographic information, “health information” necessarily includes demographic information. We think this is clear as a matter of statutory construction and does not require further regulatory change.

b. *Comment:* Several commenters asked that we clarify the difference between “health information” and “individually identifiable” and “health information pertaining to an individual” as used in the August 12, 1998 proposed rule (63 FR 43242). Additionally, commenters asked that we be more consistent in the use of these terms and recommended use of the term “individually identifiable health information.”

Two commenters stated that it is important to distinguish between “health information pertaining to an individual” and “individually identifiable health information,” as in reporting statistics at various levels there will always be a need to bring forth information pertaining to an individual.

One commenter recommended that the standards apply only to individually identifiable health information. Another

stated that in § 142.306(b) of the proposed rule, “health information pertaining to an individual” should be changed to “individually identifiable health information,” as nonidentifiable information can be used for utilization review and other purposes. As written, the regulation text could limit the ability to use data, for example, from a clearinghouse for compliance monitoring.

*Response:* In general, we agree with these commenters, and note that these comments are largely mooted by the decision, reflected in § 164.306 below and discussed in section III.D.1. of this final rule, to cover only electronic protected health information in this final rule.

c. *Comment:* Several commenters stated that the definition of “individually identifiable health information” is not in the regulations and should be added.

*Response:* We note that the definition of “individually identifiable health information” appears at § 160.103, which applies to this final rule.

### 4. Protected Health Information (§ 160.103)

This term is moved from § 164.501 to § 160.103 because it applies to both subparts C (security) and E (privacy). See 67 FR 53192 through 531936 regarding the definition of “protected health information.”

Also, the term “electronic media” is included in paragraphs (1)(i) and (ii) of the definition of “protected health information,” as specified in this section.

In addition, we added the definitions of “covered functions,” “plan sponsor,” and “Required by law” to § 164.103.

### 5. Breach (§ 164.304)

*Comment:* One commenter asked that “breach” be defined.

*Response:* The term “breach” has been deleted and therefore not defined. Instead, we define the term “security incident,” which better describes the types of situations we were referring to as breaches.

### 6. Facility (§ 164.304)

This new term has been added as a result of changing the name of the “physical access control” standard to “facility access control.” This change was made based on comments indicating that the original term was not descriptive. We have defined the term “facility” as the physical premises and interior and exterior of a building.

### 7. Security Incident (§ 164.304)

*Comment:* We received comments asking that this term be defined.

*Response:* This final rule defines “Security incident” in § 164.304 as “the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.”

### 8. System (§ 164.304)

*Comment:* One commenter asked that “system” be defined.

*Response:* This final rule defines “system,” in the context of an information system, in § 164.304 as “an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.”

### 9. Workstation (§ 164.304)

*Comment:* One commenter expressed concern that the use of the term “workstation” implied limited applicability to fixed devices (such as terminals), excluding laptops and other portable devices.

*Response:* We have added a definition of the term “workstation” to clarify that portable devices are also included. This final rule defines workstation as “an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.”

### 10. Definitions Not Adopted

Several definitions in the proposed regulations text and glossary are not adopted as definitions in the final rule: “participant,” “contingency plan,” “risk,” “role-based access control,” and “user-based access control.” The terms “participant,” “role-based access control,” and “user-based access control” are not used in this final rule and thus are not defined. “Risk” is not defined as its meaning is generally understood. While we do not define the term, we address “contingency plan” as a standard in § 164.308(a)(7) below.

a. *Comment:* We received comments requesting that we define the following terms: “token” and “documentation.”

*Response:* These terms were defined in Addendum 2 of the proposed rule. In this final rule, we do not adopt a definition for “token” because it is not used in the final rule. “Documentation” is discussed in § 164.316 below.

b. *Comment:* We received several comments that “small” and “rural” should be defined as those terms apply

to providers. We received an equal number of comments stating that there is no need to define these terms. One commenter stated that definitions for these terms would be necessary only if special exemptions existed for small and rural providers. Several commenters suggested initiation of a study to determine limitations and potential barriers small and rural providers will have in implementing these regulations.

*Response:* The statute requires that we address the needs of small and rural providers. We believe that we have done this through the provisions, which require the risk assessment and the response to be assessment based on the needs and capabilities of the entity. This scalability concept takes the needs of those providers into account and eliminates any need to define those terms.

c. *Comment:* In the proposed rule, we proposed the following definition for the term "Access control": "A method of restricting access to resources, allowing only privileged entities access. Types of access control include, among others, mandatory access control, discretionary access control, time-of-day, classification, and subject-object separation." One commenter believed the proposed definition is too restrictive and requested revision of the definition to read: "Access control refers to a method of restricting access to resources, allowing access to only those entities which have been specifically granted the desired access rights." Another commenter wanted the definition expanded to include partitioned rule-based access control (PRBAC).

*Response:* We agree with the commenter who suggested that the definition as proposed seemed too restrictive. In this case, as in many others, a number of commenters believed the examples given in the proposed rule provided the only acceptable compliance actions. As previously noted, in order to clarify that the examples listed were not to be considered all-inclusive, we have generalized the proposed requirements in this final rule. In this case, we have also generalized the requirements and placed the substantive provisions governing access control at § 164.308(a)(4), § 164.310(a)(1), and § 164.312(a)(1). With respect to PRBAC, the access control standard does not exclude this control, and entities should adopt it if appropriate to their circumstances.

#### D. General Rules (§ 164.306)

In the proposed rule, we proposed to cover all health information maintained or transmitted in electronic form by a covered entity. We proposed to adopt, in § 142.308, a nation-wide security standard that would require covered entities to implement security measures that would be technology-neutral and scalable, and yet integrate all the components of security (administrative procedures, physical safeguards, technical security services, and technical security mechanisms) that must be in place to preserve health information confidentiality, integrity, and availability (three basic elements of security). Since no comprehensive, scalable, and technology-neutral set of standards currently exists, we proposed to designate a new standard, which would define the security requirements to be fulfilled.

The proposed rule proposed to define the security standard as a set of scalable, technology-neutral requirements with implementation features that providers, plans, and clearinghouses would have to include in their operations to ensure that health information pertaining to an individual that is electronically maintained or electronically transmitted remains safeguarded. The proposed rule would have required that each affected entity assess its own security needs and risks and devise, implement, and maintain appropriate security to address its own unique security needs. How individual security requirements would be satisfied and which technology to use would be business decisions that each entity would have to make.

In the final rule we adopt this basic framework. In § 164.306, we set forth general rules pertaining to the security standards. In paragraph (a), we describe the general requirements. Paragraph (a) generally reflects section 1173(d)(2) of the Act, but makes explicit the connection between the security standards and the privacy standards (see § 164.306(a)(3)). In § 164.306(a)(1), we provide that the security standards apply to all electronic protected health information the covered entity creates, receives, maintains, or transmits. In paragraph (b)(1), we provide explicitly for the scalability of this rule by discussing the flexibility of the standards, and paragraph (b)(2) of § 164.306 discusses various factors covered entities must consider in complying with the standards.

The provisions of § 164.306(c) provide the framework for the security standards, and establish the requirement that covered entities must comply with the standards. The administrative,

physical, and technical safeguards a covered entity employs must be reasonable and appropriate to accomplish the tasks outlined in paragraphs (1) through (4) of § 164.306(a). Thus, an entity's risk analysis and risk management measures required by § 164.308(a)(1) must be designed to lead to the implementation of security measures that will comply with § 164.306(a).

It should be noted that the implementation of reasonable and appropriate security measures also supports compliance with the privacy standards, just as the lack of adequate security can increase the risk of violation of the privacy standards. If, for example, a particular safeguard is inadequate because it routinely permits reasonably anticipated uses or disclosures of electronic protected health information that are not permitted by the Privacy Rule, and that could have been prevented by implementation of one or more security measures appropriate to the scale of the covered entity, the covered entity would not only be violating the Privacy Rule, but would also not be in compliance with § 164.306(a)(3) of this rule.

Paragraph (d) of § 164.306 establishes two types of implementation specifications, required and addressable. It provides that required implementation specifications must be met. However, with respect to implementation specifications that are addressable, § 164.306(d)(3) specifies that covered entities must assess whether an implementation specification is a reasonable and appropriate safeguard in its environment, which may include consideration of factors such as the size and capability of the organization as well as the risk. If the organization determines it is a reasonable and appropriate safeguard, it must implement the specification. If an addressable implementation specification is determined not to be a reasonable and appropriate answer to a covered entity's security needs, the covered entity must do one of two things: implement another equivalent measure if reasonable and appropriate; or if the standard can otherwise be met, the covered entity may choose to not implement the implementation specification or any equivalent alternative measure at all. The covered entity must document the rationale behind not implementing the implementation specification. See the detailed discussion in section II.A.3.

Paragraph (e) of § 164.306 addresses the requirement for covered entities to maintain the security measures

implemented by reviewing and modifying the measures as needed to continue the provision of reasonable and appropriate protections, for example, as technology moves forward, and as new threats or vulnerabilities are discovered.

1. Scope of Health Information Covered by the Rule (§ 164.306(a))

We proposed to cover health information maintained or transmitted by a covered entity in electronic form. We have modified, by narrowing, the scope of health information to be safeguarded under this rule from that which was proposed. The statute requires the privacy standards to cover individually identifiable health information. The Privacy Rule covers all individually identifiable information except for: (1) Education records covered by the Family and Educational Rights and Privacy Act (FERPA); (2) records described in 20 U.S.C. 1232g(a)(4)(B)(iv); and (3) employment records. (see the Privacy Rule at 65 FR 82496. See also 67 FR 53191 through 53193). The scope of information covered in the Privacy Rule is referred to as "protected health information." Based upon the comments we received, we align the requirements of the Security and Privacy Rules with regard to the scope of information covered, in order to eliminate confusion and ease implementation. Thus, this final rule requires protection of the same scope of information as that covered by the Privacy Rule, except that it only covers that information if it is in electronic form.

We note that standards for the security of all health information or protected health information in nonelectronic form may be proposed at a later date.

a. *Comment:* One commenter stated that the rule should apply to aggregate information that is not identifiable to an individual. In contrast, another commenter asked that health information used for statistical analysis be exempted if the covered entity may reasonably expect that the removed information cannot be used to re-identify an individual.

*Response:* As a general proposition, any electronic protected health information received, created, maintained, or transmitted by a covered entity is covered by this final rule. We agree with the second commenter that certain information, from which identifiers have been stripped, does not come within the purview of this final rule. Information that is de-identified, as defined in the Privacy Rule at § 164.502(d) and § 164.514(a), is not

"individually identifiable" within the meaning of these rules and, thus, does not come within the definition of "protected health information." It accordingly is not covered by this final rule. For a full discussion of the issues of de-identification and re-identification of individually identifiable health information see 65 FR 82499 and 82708 through 82712 and 67 FR 53232 through 53234.

b. *Comment:* Several commenters asked whether systems that determine eligibility of clients for insurance coverage under broad categories such as medical coverage groups are considered health information. One commenter asked that we specifically exclude eligibility information from the standards.

*Response:* We cannot accept the latter suggestion. Eligibility information will typically be individually identifiable, and much eligibility information will also contain health information. If the information is "individually identifiable" and is "health information," (with three very specific exceptions noted in the general discussion above) and it is in electronic form, it is covered by the security standards if maintained or transmitted by a covered entity.

c. *Comment:* Several commenters requested clarification as to whether the standards apply to identifiable health information in paper form. Some commenters believed the rule should be applicable to paper; others argued that it should apply to all confidential, identifiable health information.

*Response:* While we agree that protected health information in paper or other form also should have appropriate security protections, the proposed rule proposing the security standards proposed to apply those standards to health information in electronic form only. We are, accordingly, not extending the scope in this final rule.

We may establish standards to secure protected health information in other media in a future rule, in accordance with our statutory authority to do so. See discussion, *supra*, responding to a comment on the definition of "health information" and "individually identifiable health information."

d. *Comment:* The proposed rule would have excluded "telephone voice response" and "faxback" systems from the security standards, and we specifically solicited comments on that issue. A number of commenters agreed that telephone voice response and faxback should be excluded from the regulation, suggesting that the privacy standards rather than the security standards should apply. Others wanted

those systems included, on the grounds that inclusion is necessary for consistency and in keeping with the intent of the Act. Still others specifically wanted personal computer-fax transmissions included. One commenter asked for clarification of when we would cover faxes, and another commenter asked why we were excluding them. Several commenters suggested that the other security requirements provide for adequate security of these systems.

*Response:* In light of these comments, we have decided that telephone voice response and "faxback" (that is, a request for information from a computer made via voice or telephone keypad input with the requested information returned as a fax) systems fall under this rule because they are used as input and output devices for computers, not because they have computers in them. Excluding these features would provide a huge loophole in any system concerned with security of the information contained and/or processed therein. It should be noted that employment of telephone voice response and/or faxback systems will generally require security protection by only one of the parties involved, and not the other. Information being transmitted via a telephone (either by voice or a DTMP tone pad) is not in electronic form (as defined in the first paragraph of the definition of "electronic media") before transmission and therefore is not subject to the Security Rule. Information being returned via a telephone voice response system in response to a telephone request is data that is already in electronic form and stored in a computer. This latter transmission does require protection under the Security Rule.

Although most recently made electronic devices contain microprocessors (a form of computer) controlled by firmware (an unchangeable form of computer program), we intend the term "computer" to include only software programmable computers, for example, personal computers, minicomputers, and mainframes. Copy machines, fax machines, and telephones, even those that contain memory and can produce multiple copies for multiple people are not intended to be included in the term "computer." Therefore, because "paper-to-paper" faxes, person-to-person telephone calls, video teleconferencing, or messages left on voice-mail were not in electronic form before the transmission, those activities are not covered by this rule. See also the definition of "electronic media" at § 160.103.

We note that this guidance differs from the guidance regarding the applicability of the Transactions Rule to faxback and voice response systems. HHS has stated that faxback and voice response systems are not required to follow the standards mandated in the Transactions Rule. This new guidance refers only to this rule.

e. *Comment:* One commenter asked whether there is a need to implement special security practices to address the shipping and receiving of health information and asked that we more fully explain our expectations and solutions in the final rules.

*Response:* If the handling of electronic protected health information involves shipping and receiving, appropriate measures must be taken to protect the information. However, specific solutions are not provided within this rule, as discussed in section III.A.3 of this final rule. The device and media controls standard under § 164.310(d)(1) addresses this situation.

f. *Comment:* One commenter wanted the "HTML" statement reworded to eliminate a specific exemption for HTML from the regulation.

*Response:* The Transactions Rule did not adopt the proposed exemption for HTML. The use of HTML or any other electronic protocol is not exempt from the security standards. Generally, if protected health information is contained in any form of electronic transmission, it must be appropriately safeguarded.

g. *Comment:* One commenter asked to what degree "family history" is considered health information under this rule and what protections apply to family members included in a patient's family history.

*Response:* Any health-related "family history" contained in a patient's record that identifies a patient, including a person other than the patient, is individually identifiable health information and, to the extent it is also electronic protected health information, must be afforded the security protections.

h. *Comment:* Two commenters asked that the rule prohibit re-identification of de-identified data. In contrast, several commenters asked that we identify a minimum list or threshold of specific re-identification data elements (for example, name, city, and ZIP) that would fall under this final rule so that, for example, the rule would not affect numerous systems, for example, network adequacy and population-based clinical analysis databases. One commenter asked that we establish a means to use re-identified information if the entity already has access to the

information or is authorized to have access.

*Response:* The issue of re-identification is addressed in the Privacy Rule at § 164.502(d) and § 164.514(c). The reader is referred to those sections and the related discussion in the preamble to the Privacy Rule (65 FR 82712) and the preamble to the Privacy Modifications (67 FR 53232 through 53234) for a full discussion of the issues of re-identification. We note that once information in the possession (or constructive possession) of a covered entity is re-identified and meets the definition of electronic protected health information, the security standards apply.

## 2. Technology-Neutral Standards

*Comment:* Many commenters expressed support for our efforts to develop standards for the security of health information. A number of comments were made in support of the technology-neutral approach of the proposed rule. For example, one commenter stated, "By avoiding prescription of the specific technologies health care entities should use to meet the law's requirements, you are opening the door for industry to apply innovation. Technologies that don't currently exist or are impractical today could, in the near future, enhance health information security while minimizing the overall cost." Several other commenters stated that the requirements should be general enough to withstand changes to technology without becoming obsolete. One commenter anticipates no problems with meeting the standards.

In contrast, one commenter suggested that whenever possible, specific technology recommendations should provide sufficient detail to promote systems interoperability and decrease the tendency toward adoption of multiple divergent standards. Several commenters stated that by letting each organization determine its own rules, the rules impose procedural burdens without any substantive benefit to security.

*Response:* The overwhelming majority of comments supported our position. We do not believe it is appropriate to make the standards technology-specific because technology is simply moving too fast, for example, the increased use and sophistication of internet-enabled hand held devices. We believe that the implementation of these rules will promote the security of electronic protected health information by (1) providing integrity and confidentiality; (2) allowing only authorized individuals

access to that information; and (3) ensuring its availability to those authorized to access the information. The standards do not allow organizations to make their own rules, only their own technology choices.

## 3. Miscellaneous Comments

a. *Comment:* Some commenters stated that the requirements and implementation features set out in the proposed rule were not specific enough to be considered standards, and that the actual standards are delegated to the discretion of the covered entities, at the expense of medical record privacy. Several commenters stated that it was inappropriate to balance the interests of those seeking to use identifiable medical information without patient consent against the interest of patients. Several other commenters believe that allowing covered entities to make their own decisions about the adequacy and balance of security measures undermined patient confidentiality interests, and stated that the proposed rule did not appear to adequately consider patient concerns and viewpoints.

*Response:* Again, the overwhelming majority of commenters supported our approach. This final rule sets forth requirements with which covered entities must comply and labels those requirements as standards and implementation specifications. Adequate implementation of this final rule by covered entities will ensure that the electronic protected health information in a covered entity's care will be as protected as is feasible for that entity.

We disagree that covered entities are given complete discretion to determine their security policies under this rule, resulting in effect, in no standards. While cost is one factor a covered entity may consider in determining whether to implement a particular implementation specification, there is nonetheless a clear requirement that adequate security measures be implemented, see 45 CFR 164.306(b). Cost is not meant to free covered entities from this responsibility.

b. *Comment:* Several commenters requested we withdraw the regulations, citing resource shortages due to Y2K preparation, upcoming privacy legislation, and/or the "excessive micro-management" contained in the rules. One commenter stated that, to insurers, these rules were onerous, not necessary, and not justified as cost-effective, as they already have effective practices for computer security and are subject to rigorous State laws for the safeguarding of health information. Another

commenter stated that these rules would adversely affect a provider's practice environment.

*Response:* The HIPAA statute requires us to promulgate a rule adopting security standards for health information. Resource concerns due to Y2K should no longer be an issue. Covered entities will have 2 years (or, in the case of small health plans, 3 years) from the adoption of this final rule in which to comply. Concerns relative to effective and compliance dates and the Privacy Rule are discussed under § 164.318, Compliance dates for initial implementation, below and at 65 FR 82751 through 82752.

We disagree that these standards will adversely affect a provider's practice environment. The scalability of the standards allows each covered entity to implement security protections that are appropriate to its specific needs, risks, and environments. These protections are necessary to maintain the confidentiality, integrity, and availability of patient data. A covered entity that lacks adequate protections risks inadvertent disclosure of patient data, with resulting loss of public trust, and potential legal action. For example, a covered entity with poor facility access controls and procedures would be susceptible to hacking of its databases. A provider with appropriate security protections already in place would only need to ensure that the protections are documented and are reassessed periodically to ensure that they continue to be appropriate and are actually being implemented. Our decision to classify many implementation specifications as addressable, rather than mandatory, provides even more flexibility to covered entities to develop cost-effective solutions. We believe that insurers who already have effective security programs in place will have met many of the requirements of this regulation.

c. *Comment:* One commenter believes the rule is arbitrary and capricious in its requirements without any justification that they will significantly improve the security of medical records and with the likelihood that their implementation may actually increase the vulnerability of the data. The commenter noted that the data backup requirements increase access to data and that security awareness training provides more information to employees.

*Response:* The standards are based on generally accepted security procedures, existing industry standards and guidelines, and recommendations contained in the National Research Council's 1997 report *For The Record:*

#### *Protecting Electronic Health*

*Information*, Chapter 6. We also consulted extensively with experts in the field of security throughout the health care industry. The standards are consistent with generally accepted security principles and practices that are already in widespread use.

Data backup need not result in increased access to that data. Backups should be stored in a secure location with controlled access. The appropriate secure location and access control will vary, based upon the security needs of the covered entity. For example, a procedure as simple as locking backup diskettes in a safe place and restricting who has access to the key may be suitable for one entity, whereas another may need to store backed-up information off-site in a secure computer facility. The information provided in security awareness training heightens awareness of security anomalies and helps to prevent security incidents.

d. *Comment:* Several commenters suggested that the proposed rule appears to reflect the Medicare program's perspective on security risks and solutions, and that it should be noted that not all industry segments share all the same risks as Medicare. One commenter stated that as future proposed rules are drafted, we should solicit input from those most significantly affected, for example, providers, plans, and clearinghouses.

Others stated that Medicaid agencies were not sufficiently involved in the discussions and debate. Still another stated that States would be unable to perform some basic business functions if all the standards are not designed to meet their needs.

*Response:* We believe that the standards are consistent with common industry practices and equitable, and that there has been adequate consultation with interested parties in the development of the standards. These standards are the result of an intensive process of public consultation. We consulted with the National Uniform Billing Committee, the National Uniform Claim Committee, the American Dental Association, and the Workgroup for Electronic Data Interchange, in the course of developing the proposed rule. Those organizations were specifically named in the Act to advise the Secretary, and their membership is drawn from the full spectrum of industry segments. In addition, the National Committee on Vital and Health Statistics (NCVHS), an independent advisory group to the Secretary, held numerous public hearings to obtain the views of

interested parties. Again, many segments of the health care industry, including provider groups, health plans, clearinghouses, vendors, and government programs participated actively. The NCVHS developed recommendations to the Secretary, which were relied upon as we developed the proposed rule. Finally, we note that the opportunity to comment was available to all during the public comment period.

e. *Comment:* One commenter stated that there is a need to ensure the confidentiality of risk analysis information that may contain sensitive information.

*Response:* The information included in a risk analysis would not be subject to the security standards if it does not include electronic protected health information. We agree that risk analysis data could contain sensitive information, just as other business information can be sensitive. Covered entities may wish to develop their own business rules regarding access to and protections for risk analysis data.

f. *Comment:* One commenter expressed concern over the statement in the preamble of the proposed rule (63 FR 43250) that read: "No one item is considered to be more important than another." The commenter suggested that security management should be viewed as most critical and perhaps what forms the foundation for all other security actions.

*Response:* The majority of comments received on this subject requested that we prioritize the standards. In response, we have regrouped the standards and implementation specifications in what we believe is a logical order within each of three categories: "Administrative safeguards," "Physical safeguards," and "Technical safeguards." In this final rule, we order the standards in such a way that the "Security management process" is listed first under the "Administrative safeguards" section, as we believe this forms the foundation on which all of the other standards depend. The determination of the specific security measures to be implemented to comply with the standards will, in large part, be dependent upon completion of the implementation specifications within the security management process standard (see § 164.308(a)(1)). We emphasize, however, that an entity implementing these standards may choose to implement them in any order, as long as the standards are met.

g. *Comment:* One commenter stated that there is a need for requirements concerning organizational practices (for example, education, training, and security and confidentiality policies), as

well as technical practices and procedures.

*Response:* We agree. Section 164.308 of this final rule describes administrative safeguards that address these topics. Section 164.308 requires covered entities to implement standards and required implementation specifications, as well as consider and implement, when appropriate and reasonable, addressable implementation specifications. For example, the security management process standard requires implementation of a risk analysis, risk management, a sanction policy, and an information system activity review. The information access management standard requires consideration, and implementation where appropriate and reasonable, of access authorization and access establishment and modification policies and procedures. Other areas addressed are assigned security responsibility, workforce security, security awareness and training, security incident procedures, contingency planning, business associate contracts, and evaluation.

*h. Comment:* One commenter stated that internal and external security requirements should be separated and dealt with independently.

*Response:* The presentation of the standards within this final rule could have been structured in numerous ways, including by addressing separate internal and external security standards. We chose the current structure as we considered it a logical breakout for purposes of display within this final rule. Under our structure a covered entity may apply a given standard to internal activities and to external activities. Had we displayed separately the standards for internal security and the standards for external security, we would have needed to describe a number of the standards twice, as many apply to both internal and external security. However, a given entity may address the standards in whatever order it chooses, as long as the standards are met.

*i. Comment:* Two commenters stated that the standards identified in Addendum 3 of the proposed rule may not all have matured to implementation readiness.

*Response:* Addendum 3 of the proposed rule cross-referenced individual requirements on the matrix to existing industry standards of varying levels of maturity. Addendum 3 was intended to show what we evaluated in searching for existing industry standards that could be adopted on a national level. No one standard was found to be comprehensive enough to be adopted, and none were proposed as the

standards to be met under the Security Rule.

*j. Comment:* One commenter suggested we include a revised preamble in the final publication. Another questioned how clarification of points in the preamble will be handled if the preamble is not part of the final regulation.

*Response:* Preambles to proposed rules are not republished in the final rule. The preamble in this final rule contains summaries of the information presented in the preamble of the proposed rule, summaries of the comments received during the public comment period, and responses to questions and concerns raised in those comments and a summary of changes made. Additional clarification will be provided by HHS on an ongoing basis through written documents and postings on HHS's websites.

*k. Comment:* One commenter asked that we clarify that no third party can require implementation of more security features than are required in the final rule, for example, a third party could not require encryption but may choose to accept it if the other party so desires.

*Response:* The security standards establish a minimum level of security to be met by covered entities. It is not our intent to limit the level of security that may be agreed to between trading partners or others above this floor.

*l. Comment:* One commenter asked how privacy legislation would affect these rules. The commenter inquired whether covered entities will have to reassess and revise actions already taken in the spirit of compliance with the security regulations.

*Response:* We cannot predict if or how future legislation may affect the rules below. At present, the privacy standards at subpart E of 42 CFR part 164 have been adopted, and this final rule is compatible with them.

*m. Comment:* One commenter stated that a data classification policy, that is a method of assigning sensitivity ratings to specific pieces of data, should be part of the final regulations.

*Response:* We did not adopt such a policy because this final rule requires a floor of protection of all electronic protected health information. A covered entity has the option to exceed this floor. The sensitivity of information, the risks to and vulnerabilities of electronic protected health information and the means that should be employed to protect it are business determinations and decisions to be made by each covered entity.

*n. Comment:* One commenter stated that this proposed rule conflicts with previously stated rules that acceptable

“standards” must have been developed by ANSI-recognized Standards Development Organizations (SDOs).

*Response:* In general, HHS is required to adopt standards developed by ANSI-accredited SDOs when such standards exist. The currently existing security standards developed by ANSI-recognized SDOs are targeted to specific technologies and/or activities. No existing security standard, or group of standards, is technology-neutral, scaleable to the extent required by HIPAA, and broad enough to be adopted in this final rule. Therefore, this final rule adopts standards under section 1172(c)(2)(B) of the Act, which permits us to develop standards when no industry standards exist.

*o. Comment:* One commenter stated that this regulation goes beyond the scope of the law, unjustifiably extending into business practices, employee policies, and facility security.

*Response:* We do not believe that this regulation goes beyond the scope of the law. The law requires HHS to adopt standards for reasonable and appropriate security safeguards concerning such matters as compliance by the officers and employees of covered entities, protection against reasonably anticipated unauthorized uses and disclosures of health information, and so on. Such standards will inevitably address the areas the commenter pointed to.

The intent of this regulation is to provide standards for the protection of electronic protected health information in accordance with the Act. In order to do this, covered entities are required to implement administrative, physical, and technical safeguards. Those entities must ensure that data are protected, to the extent feasible, from inappropriate access, modification, dissemination, and destruction. As noted above, however, this final rule has been modified to increase flexibility as to how this protection is accomplished.

*p. Comment:* One commenter stated that all sections regarding confidentiality and privacy should be removed, since they do not belong in this regulation.

*Response:* As the discussion in section III.A above of this final rule makes clear, the privacy and security standards are very closely related. Section 1173(d)(2) of the Act specifically mentions “confidentiality” and authorizes uses and disclosures of information as part of what security safeguards must address. Thus, we cannot omit all references to confidentiality and privacy in discussions of the security standards.



However, we have relocated material that relates to both security and privacy (including definitions) to the general section of part 164.

*q. Comment:* One commenter asked that data retention be addressed more specifically, since this will become a significant issue over time. It is recommended that a national work group be convened to address this issue.

*Response:* The commenter's concern is noted. While the documentation relating to Security Rule implementation must be retained for a period of 6 years (see § 164.316(b)(2)), it is not within the scope of this final rule to address data retention time frames for administrative or clinical records.

*r. Comment:* One commenter stated that requiring provider practices to develop policies, procedures, and training programs and to implement record keeping and documentation systems would be tremendously resource-intensive and increase the costs of health care.

*Response:* We expect that many of the standards of this final rule are already being met in one form or another by covered entities. For example, as part of normal business operations, health care providers already take measures to protect the health information in their keeping. Health care providers already keep records, train their employees, and require employees to follow office policies and procedures. Similarly, health plans are already frequently required by State law to keep information confidential. While revisions to a practice's or plan's current activities may be necessary, the development of entirely new systems or procedures may not be necessary.

*s. Comment:* One commenter stated that there is no system for which risk has been eliminated and expressed concern over phrases such as covered entities must "assure that electronic health information pertaining to an individual remains secure."

*Response:* We agree with the commenter that there is no such thing as a totally secure system that carries no risks to security. Furthermore, we believe the Congress' intent in the use of the word "ensure" in section 1173(d) of the Act was to set an exceptionally high goal for the security of electronic protected health information. However, we note that the Congress also recognized that some trade-offs would be necessary, and that "ensuring" protection did not mean providing protection, no matter how expensive. See section 1173(d)(1)(A)(ii) of the Act. Therefore, when we state that a covered entity must ensure the safety of the information in its keeping, we intend

that a covered entity take steps, to the best of its ability, to protect that information. This will involve establishing a balance between the information's identifiable risks and vulnerabilities, and the cost of various protective measures, and will also be dependent upon the size, complexity, and capabilities of the covered entity, as provided in § 164.306(b).

#### *E. Administrative Safeguards (§ 164.308)*

We proposed that measures taken to comply with the rule be appropriate to protect the health information in a covered entity's care. Most importantly, we proposed to require that both the measures taken and documentation of those measures be kept current, that is, reviewed and updated periodically to continue appropriately to protect the health information in the care of covered entities. We would have required the documentation to be made available to those individuals responsible for implementing the procedure.

We proposed a number of administrative requirements and supporting implementation features, and required documentation for those administrative requirements and implementation features.

In this final rule, we have placed these administrative standards in § 164.308. We have reordered them, deleted much of the detail of the proposed requirements, as discussed below, and omitted two of the proposed sets of requirements (system configuration requirements and a requirement for a formal mechanism for processing records) as discussed in paragraph 10 of the discussion of § 164.308 of section III.E. of this preamble. Otherwise, the basic elements of the administrative safeguards are adopted in this final rule as proposed.

#### *1. Security Management Process (§ 164.308(a)(1)(i))*

We proposed the establishment of a formal security management process to involve the creation, administration, and oversight of policies to address the full range of security issues and to ensure the prevention, detection, containment, and correction of security violations. This process would include implementation features consisting of a risk analysis, risk management, and sanction and security policies.

We also proposed, in a separate requirement under administrative procedures, an internal audit, which would be an in-house review of the records of system activity (for example,

logins, file accesses, and security incidents) maintained by an entity.

In this final rule, risk analysis, risk management, and sanction policy are adopted as required implementation specifications although some of the details are changed, and the proposed internal audit requirement has been renamed as "information system activity review" and incorporated here as an additional implementation specification.

*a. Comment:* Three commenters asked that this requirement be deleted. Two commenters cited this requirement as a possible burden. Several commenters asked that the implementation features be made optional.

*Response:* This standard and its component implementation specifications form the foundation upon which an entity's necessary security activities are built. See NIST SP 800-30, "Risk Management Guide for Information Technology Systems," chapters 3 and 4, January 2002. An entity must identify the risks to and vulnerabilities of the information in its care before it can take effective steps to eliminate or minimize those risks and vulnerabilities. Some form of sanction or punishment activity must be instituted for noncompliance. Indeed, we question how the statutory requirement for safeguards "to ensure compliance \* \* \* by a [covered entity's] officers and employees" could be met without a requirement for a sanction policy. See section 1176(d)(2)(C) of the Act. Accordingly, implementation of these specifications remains mandatory. However, it is important to note that covered entities have the flexibility to implement the standard in a manner consistent with numerous factors, including such things as, but not limited to, their size, degree of risk, and environment. We have deleted the implementation specification calling for an organizational security policy, as it duplicated requirements of the security management and training standard.

We note that the implementation specification for a risk analysis at § 164.308(a)(1)(ii)(A) does not specifically require that a covered entity perform a risk analysis often enough to ensure that its security measures are adequate to provide the level of security required by § 164.306(a). In the proposed rule, an assurance of adequate security was framed as a requirement to keep security measures "current." We continue to believe that security measures must remain current, and have added regulatory language in § 164.306(e) as a more precise way of communicating that security measures



in general that must be periodically reassessed and updated as needed.

The risk analysis implementation specification contains other terms that merit explanation. Under § 164.308(a)(1)(ii)(A), the risk analysis must look at risks to the covered entity's electronic protected health information. A thorough and accurate risk analysis would consider "all relevant losses" that would be expected if the security measures were not in place. "Relevant losses" would include losses caused by unauthorized uses and disclosures and loss of data integrity that would be expected to occur absent the security measures.

b. *Comment:* Relative to the development of an entity's sanction policy, one commenter asked that we describe the sanction penalties for breach of security. Another suggested establishment of a standard to which one's conduct could be held and adoption of mitigating circumstances so that the fact that a person acted in good faith would be a factor that could be used to reduce or otherwise minimize any sanction imposed. Another commenter suggested sanction activities not be implemented before the full implementation and testing of all electronic transaction standards.

*Response:* The sanction policy is a required implementation specification because—(1) the statute requires covered entities to have safeguards to ensure compliance by officers and employees; (2) a negative consequence to noncompliance enhances the likelihood of compliance; and (3) sanction policies are recognized as a usual and necessary component of an adequate security program. The type and severity of sanctions imposed, and for what causes, must be determined by each covered entity based upon its security policy and the relative severity of the violation.

c. *Comment:* Commenters requested the definitions of "risk analysis" and "breach."

*Response:* "Risk analysis" is defined and described in the specification of the security management process standard, and is discussed in the preamble discussion of § 164.308(a)(1)(ii)(A) of this final rule. The term breach is no longer used and is, therefore, not defined.

d. *Comment:* One commenter asked whether all health information is considered equally "sensitive," the thought being that, in determining risk, an entity may consider the loss of a smaller amount of extraordinarily sensitive data to be more significant than the loss of a larger amount of routinely collected data. The commenter

stated that common reasoning would suggest that the smaller amount of data would be considered more sensitive.

*Response:* All electronic protected health information must be protected at least to the degree provided by these standards. If an entity desires to protect the information to a greater degree than the risk analysis would indicate, it is free to do so.

e. *Comment:* One commenter asked that we add "threat assessment" to this requirement.

*Response:* We have not done this because we view threat assessment as an inherent part of a risk analysis; adding it would be redundant.

f. *Comment:* We proposed a requirement for internal audit, the in-house review of the records of system activity (for example, logins, file accesses, and security incidents) maintained by an entity. Several commenters wanted this requirement deleted. One suggested the audit trail requirement should not be mandatory, while another stated that internal audits would be unnecessary if physical security requirements are implemented.

A number of commenters asked that we clarify the nature and scope of what an internal audit covers and what the audit time frame should be. Several commenters offered further detail concerning what should and should not be required in an internal audit for security purposes. One commenter stated that ongoing intrusion detection should be included in this requirement. Another wanted us to specify the retention times for archived audit logs.

Several commenters had difficulty with the term "audit" and suggested we change the title of the requirement to "logging and violation monitoring."

A number of commenters stated this requirement could result in an undue burden and would be economically unfeasible.

*Response:* Our intent for this requirement was to promote the periodic review of an entity's internal security controls, for example, logs, access reports, and incident tracking. The extent, frequency, and nature of the reviews would be determined by the covered entity's security environment. The term "internal audit" apparently, based on the comments received, has certain rigid formal connotations we did not intend. We agree that the implementation of formal internal audits could prove burdensome or even unfeasible, to some covered entities due to the cost and effort involved. However, we do not want to overlook the value of internal reviews. Based on our review of the comments and the text to which they refer, it is clear that this

requirement should be renamed for clarity and that it should actually be an implementation specification of the security management process rather than an independent standard. We accordingly remove "internal audit" as a separate requirement and add "information system activity review" under the security management process standard as a mandatory implementation specification.

## 2. Assigned Security Responsibility (§ 164.308(a)(2))

We proposed that the responsibility for security be assigned to a specific individual or organization to provide an organizational focus and importance to security, and that the assignment be documented. Responsibilities would include the management and supervision of (1) the use of security measures to protect data, and (2) the conduct of personnel in relation to the protection of data.

In this final rule, we clarify that the final responsibility for a covered entity's security must be assigned to one official. The requirement for documentation is retained, but is made part of § 164.316 below. This policy is consistent with the analogous policy in the Privacy Rule, at 45 CFR 164.530(a), and the same considerations apply. See 65 FR 82744 through 87445. The same person could fill the role for both security and privacy.

a. *Comment:* Commenters were concerned that delegation of assigned security responsibility, especially in large organizations, needs to be to more than a single individual. Commenters believe that a large health organization's security concerns would likely cross many departmental boundaries requiring group responsibility.

*Response:* The assigned security responsibility standard adopted in this final rule specifies that final security responsibility must rest with one individual to ensure accountability within each covered entity. More than one individual may be given specific security responsibilities, especially within a large organization, but a single individual must be designated as having the overall final responsibility for the security of the entity's electronic protected health information. This decision also aligns this rule with the final Privacy Rule provisions concerning the Privacy Official.

b. *Comment:* One commenter disagreed with placing assigned security responsibility as part of physical safeguards. The commenter suggested that assigned security responsibility should be included under the Administrative Procedures.

*Response:* Upon review of the matrix and regulations text, we agree with the commenter, because this requirement involves an administrative decision at the highest levels of who should be responsible for ensuring security measures are implemented and maintained. Assigned security responsibility has been removed from "Physical safeguards" and is now located under "Administrative safeguards" at § 164.308.

### 3. Workforce Security (§ 164.308(a)(3)(i))

We proposed implementation of a number of features for personnel security, including ensuring that maintenance personnel are supervised by a knowledgeable person, maintaining a record of access authorizations, ensuring that operating and maintenance personnel have proper access authorization, establishing personnel clearance procedures, establishing and maintaining personnel security policies and procedures, and ensuring that system users have proper training.

In this final rule, to provide clarification and reduce duplication, we have combined the "Assure supervision of maintenance personnel by authorized, knowledgeable person" implementation feature and the "Operating, and in some cases, maintenance personnel have proper access authorization" feature into one addressable implementation specification titled "Authorization and/or supervision."

In a related, but separate, requirement entitled "Termination procedures," we proposed implementation features for the ending of an employee's employment or an internal or external user's access. These features would include things such as changing combination locks, removal from access lists, removal of user account(s), and the turning in of keys, tokens, or cards that allow access.

In this final rule, "Termination procedures" has been made an addressable implementation specification under "Workforce security." This is addressable because in certain circumstances, for example, a solo physician practice whose staff consists only of the physician's spouse, formal procedures may not be necessary.

The proposed "Personnel security policy/procedure" and "record of access authorizations" implementation features have been removed from this final rule, as they have been determined to be redundant. Implementation of the balance of the "Workforce security" implementation specifications and the

other standards contained within this final rule will result in assurance that all personnel with access to electronic protected health information have the required access authority as well as appropriate clearances.

a. *Comment:* The majority of comments concerned the supervision of maintenance personnel by an authorized knowledgeable person. Commenters stated this would not be feasible in smaller settings. For example, the availability of technically knowledgeable persons to ensure this supervision would be an issue. We were asked to either reword this implementation feature or delete it.

*Response:* We agree that a "knowledgeable" person may not be available to supervise maintenance personnel. We have accordingly modified this implementation specification so that, in this final rule, we are adopting an addressable implementation specification titled, "Authorization and/or supervision," requiring that workforce members, for example, operations and maintenance personnel, must either be supervised or have authorization when working with electronic protected health information or in locations where it resides (see § 164.308(a)(3)(ii)(A)). Entities can decide on the feasibility of meeting this specification based on their risk analysis.

b. *Comment:* The second largest group of comments requested assurance that, with regard to the proposed "Personnel clearance procedure" implementation feature, having appropriate clearances does not mean performing background checks on everyone. We were asked to delete references to "clearance" and use the term "authorization" in its place.

*Response:* We agree with the commenters concerning background checks. This feature was not intended to be interpreted as an absolute requirement for background checks. We retain the use of the term "clearance," however, because we believe that it more accurately conveys the screening process intended than does the term "authorization." We have attempted to clarify our intent in the language of § 164.308(a)(3)(ii)(B), which now reads, "Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate." The need for and extent of a screening process is normally based on an assessment of risk, cost, benefit, and feasibility as well as other protective measures in place. Effective personnel screening processes may be applied in a way to allow a range of implementation, from minimal procedures to more stringent procedures

based on the risk analysis performed by the covered entity. So long as the standard is met and the underlying standard of § 164.306(a) is met, covered entities have choices in how they meet these standards. To clarify the intent of this provision, we retitle the implementation specification "Workforce clearance procedure."

c. *Comment:* One commenter asked that we expand the implementation features to include the identification of the restrictions that should be placed on members of the workforce and others.

*Response:* We have not adopted this comment in the interest of maintaining flexibility as discussed in § 164.306. Restrictions would be dependent upon job responsibilities, the amount and type of supervision required and other factors. We note that a covered entity should consider in this regard the applicable requirements of the Privacy Rule (see, for example, § 164.514(d)(2) (relating to minimum necessary requirements), and § 164.530(c) (relating to safeguards).

*Comment:* One commenter believes that the proposed "Personnel security" requirement was reasonable, since an administrative determination of trustworthiness is needed before allowing access to sensitive information. Two commenters asked that we delete the requirement entirely. A number of commenters requested that we delete the implementation features. Another commenter stated that all the implementation features may not be applicable or even appropriate to a given entity and should be so qualified.

*Response:* While we do not believe this requirement should be eliminated, we agree that all the implementation specifications may not be applicable or even appropriate to a given entity. For example, a personal clearance may not be reasonable or appropriate for a small provider whose only assistant is his or her spouse. The implementation specifications are not mandatory, but must be addressed. This final rule has been changed to reflect this approach (see § 164.308(a)(3)(ii)(B)).

e. *Comment:* The majority of commenters on the "Termination procedures" requirement asked that it be made optional, stating that it may not be applicable or even appropriate in all circumstances and should be so qualified or posed as guidelines. A number of commenters stated that the requirement should be deleted. One commenter stated that much of the material covered under the "Termination procedures" requirement is already covered in "Information access control." A number of commenters stated that this requirement

was too detailed and some of the requirements excessive.

*Response:* Based upon the comments received, we agree that termination procedures should not be a separate standard; however, consideration of termination procedures remains relevant for any covered entity with employees, because of the risks associated with the potential for unauthorized acts by former employees, such as acts of retribution or use of proprietary information for personal gain. We further agree with the reasoning of the commenters who asked that these procedures be made optional; therefore, "Termination procedures" is now reflected in this final rule as an addressable implementation specification. We also removed reference to all specific termination activities, for example, changing locks, because, although the activities may be considered appropriate for some covered entities, they may not be reasonable for others.

f. *Comment:* One commenter asked whether human resource employee termination policies and procedures must be documented to show the types of security breaches that would result in termination.

*Response:* Policies and procedures implemented to adhere to this standard must be documented (see § 164.316 below). The purpose of termination procedure documentation under this implementation specification is not to detail when or under which circumstances an employee should be terminated. This information would more appropriately be part of the entity's sanction policy. The purpose of termination procedure documentation is to ensure that termination procedures include security-unique actions to be followed, for example, revoking passwords and retrieving keys when a termination occurs.

#### 4. Information Access Management (§ 164.308(a)(4))

We proposed an "information access control" requirement for establishment and maintenance of formal, documented policies and procedures defining levels of access for all personnel authorized to access health information, and how access is granted and modified. In § 164.308(a)(4)(ii)(B) and (C) below, the proposed implementation features are made addressable specifications. We have added in § 164.308(a)(4)(ii)(A), a required implementation specification to isolate health care clearinghouse functions to address the provisions of section 1173(d)(1)(B) of the Act which related to this area.

a. *Comment:* One commenter asked that the requirement be deleted, expressing the opinion that this requirement goes beyond "reasonable boundaries" into regulating common business practices. In contrast, another asked that we expand this requirement to identify participating parties and access privileges relative to specific data elements.

*Response:* We disagree that this requirement improperly imposes upon business functions. Restricting access to those persons and entities with a need for access is a basic tenet of security. By this mechanism, the risk of inappropriate disclosure, alteration, or destruction of information is minimized. We cannot, however, specifically identify participating parties and access privileges relative to data elements within this regulation. These will vary depending upon the entity, the needs within the user community, the system in which the data resides, and the specific data being accessed. This standard is consistent with § 164.514(d) in the Privacy Rule (minimum necessary requirements for use and disclosure of protected health information), and is, therefore, being retained.

b. *Comment:* Several commenters asked that we not mandate the implementation features, but leave them as optional, a suggested means of compliance. The commenters noted that this might make the rules more scalable and flexible, since this approach would allow providers to implement safeguards that best addressed their needs. Along this line, one commenter expressed the belief that each organization should implement features deemed necessary based on its own risk assessment.

*Response:* While the information access management standard in this final rule must be met, we agree that the implementation specifications at § 164.308(a)(4)(ii)(B) and (C) should not be mandated but posed as a suggested means of compliance, which must be addressed. These specifications may not be applicable to all entities based on their size and degree of automation. A fully automated covered entity spanning multiple locations and involving hundreds of employees may determine it has a need to adopt a formal policy for access authorization, while a small provider may decide that a desktop standard operating procedure will meet the specifications. The final rule has been revised accordingly.

c. *Comment:* Clarification was requested concerning the meaning of "formal."

*Response:* The word "formal" has caused considerable concern among commenters, as it was thought "formal" carried the connotation of a rigidly defined structure similar to what might be found in the Department of Defense instructions. As used in the proposed rule, this word was not intended to convey such a strict structure. Rather, it was meant to convey that documentation should be an official organizational statement as opposed to word-of-mouth or cryptic notes scratched on a notepad. While documentation is still required (see § 164.316), to alleviate confusion, the word "formal" has been deleted.

d. *Comment:* One commenter asked that we clarify that this requirement relates to both the establishment of policies for the access control function and to access control (the implementation of those policies).

*Response:* "Information access management" does address both the establishment of access control policies and their implementation. We use the term "implement" to clarify that the procedures must be in use, and we believe that the requirement to implement policies and procedures requires, as an antecedent condition, the establishment or adaptation of those policies and procedures.

#### 5. Security Awareness and Training (§ 164.308(a)(5)(i))

We proposed, under the requirement "Training," that security training be required for all staff, including management. Training would include awareness training for all personnel, periodic security reminders, user education concerning virus protection, user education in the importance of monitoring login success/failure, and how to report discrepancies, and user education in password management.

In this final rule, we adopt this proposed requirement in modified form. For the standard "Security awareness and training," in § 164.308(a)(5), we require training of the workforce as reasonable and appropriate to carry out their functions in the facility. All proposed training features have been combined as implementation specifications under this standard. Specific implementation specifications relative to content are addressable. The "Virus protection" implementation feature has been renamed "protection from malicious software," because we did not intend by the nomenclature to exclude coverage of malicious acts that might not come within the prior term, such as worms.

a. *Comment:* One commenter believes that security awareness training for all

system users would be too difficult to do in a large organization.

*Response:* We disagree with the commenter. Security awareness training is a critical activity, regardless of an organization's size. This feature would typically become part of an entity's overall training program (which would include privacy and other information technology items as well). For example, the Government Information Systems Reform ACT (GISRA) of 2000 requires security awareness training as part of Federal agencies' information security programs, including Federal covered entities, such as the Medicare program. In addition, National Institute of Standards and Technology (NIST) SP 800-16, *Information Technology Security Training Requirements, A role and performance base model*, April 1998, provides an excellent source of information and guidance on this subject and is targeted at industry as well as government activities. We also note that covered entities must have discretion in how they implement the requirement, so they can incorporate this training in other existing activities. One approach would be to require this training as part of employee orientation.

b. *Comment:* A number of commenters asked that this requirement be made optional or used as a guideline only. Several commenters stated that this requirement is too specific and is burdensome. Several asked that the implementation features be removed.

Several others stated that this requirement is not appropriate for agents or contractors. One commenter asked how to apply this requirement to outsiders having access to data. Another asked if this requirement included all subcontractor staff. Others stated that contracts, signed by entities such as consultants, that address training should be sufficient.

*Response:* Security training remains a requirement because of its criticality; however, we have revised the implementation specifications to indicate that the amount and type of training needed will be dependent upon an entity's configuration and security risks. Business associates must be made aware of security policies and procedures, whether through contract language or other means. Covered entities are not required to provide training to business associates or anyone else that is not a member of their workforce.

c. *Comment:* Several commenters questioned why security awareness training appeared in two places, under "Physical safeguards" as well as "Administrative safeguards." Others questioned the appropriateness of

security awareness training under "Physical safeguards."

*Response:* We reviewed the definitions of the proposed "Awareness training for all personnel" ("Administrative safeguards") implementation feature and the proposed "Security awareness training" ("Physical safeguards") requirement. We agree that, to avoid confusion and eliminate redundancy, security awareness and training should appear in only one place. We believe the appropriate location for it is under "Administrative safeguards," as such training is essentially an administrative function.

d. *Comment:* Several commenters objected to the blanket requirement for security awareness training of individuals who may be on site for a limited time period (for example, a single day).

*Response:* Each individual who has access to electronic protected health information must be aware of the appropriate security measures to reduce the risk of improper access, uses, and disclosures. This requirement does not mean lengthy training is appropriate in every instance; there are alternative methods to inform individuals of security responsibilities (for example, provisions of pamphlets or copies of security policies, and procedures).

e. *Comment:* One commenter asked that "training" be changed to "orientation."

*Response:* We believe the term "training," as presented within this rule is the more appropriate term. The rule does not contemplate a one-time type of activity as connoted by "orientation," but rather an on-going, evolving process as an entity's security needs and procedures change.

f. *Comment:* Several commenters asked how often training should be conducted and asked for a definition of "periodic," as it appears in the proposed implementation feature "Periodic security reminders." One asked if the training should be tailored to job need.

*Response:* Amount and timing of training should be determined by each covered entity; training should be an on-going, evolving process in response to environmental and operational changes affecting the security of electronic protected health information. While initial training must be carried out by the compliance date, we provide flexibility for covered entities to construct training programs. Training can be tailored to job need if the covered entity so desires.

6. Security Incident Procedures (§ 164.308(a)(6))

We proposed a requirement for implementation of accurate and current security incident procedures: formal, documented report and response procedures so that security violations would be reported and handled promptly. We adopt this standard in the final rule, along with an implementation specification for response and reporting, since documenting and reporting incidents, as well as responding to incidents are an integral part of a security program.

a. *Comment:* Several commenters asked that we further define the scope of a breach of security. Along this same line, another commenter stated that the proposed security incident procedures were too vague as stated. We were asked to specify what a security incident would be, what the internal chain for reporting procedures would be, and what should be included in the documentation (for example, hardware/software, personnel responses).

*Response:* We define a security incident in § 164.304. Whether a specific action would be considered a security incident, the specific process of documenting incidents, what information should be contained in the documentation, and what the appropriate response should be will be dependent upon an entity's environment and the information involved. An entity should be able to rely upon the information gathered in complying with the other security standards, for example, its risk assessment and risk management procedures and the privacy standards, to determine what constitutes a security incident in the context of its business operations.

b. *Comment:* One commenter asked what types of incidents must be reported to outside entities. Another commented that we clarify that incident reporting is internal.

*Response:* Internal reporting is an inherent part of security incident procedures. This regulation does not specifically require any incident reporting to outside entities. External incident reporting is dependent upon business and legal considerations.

c. *Comment:* One commenter stated that network activity should be included here.

*Response:* We see no reason to exclude network activity under this requirement. Improper network activity should be treated as a security incident, because, by definition, it represents an improper instance of access to or use of information.

d. *Comment:* One commenter stated that this requirement should address suspected misuse also.

*Response:* We agree that security incidents include misuse of data; therefore, this requirement is addressed.

e. *Comment:* Several commenters asked that this requirement be deleted. One commenter asked that we delete the implementation features.

*Response:* As indicated above, we have adopted the proposed standard and combined the implementation specifications.

#### 7. Contingency Plan (§ 164.308(a)(7)(i))

We proposed that a contingency plan must be in effect for responding to system emergencies. The plan would include an applications and data criticality analysis, a data backup plan, a disaster recovery plan, an emergency mode operation plan, and testing and revision procedures.

In this final rule, we make the implementation specifications for testing and revision procedures and an applications and data criticality analysis addressable, but otherwise require that the contingency features proposed be met.

a. *Comment:* Several commenters suggested the contingency plan requirement be deleted. Several thought that this aspect of the proposed regulation went beyond its intended scope. Another believed that more discussion and development is needed before developing regulatory guidance on contingency plans. Others wanted this to be an optional requirement. In contrast, one commenter requested more guidance concerning contingency planning. Still others wanted to require that a contingency plan be in place but stated that we should not regulate its contents. One comment stated that data backup, disaster recovery, and emergency mode operation should not be part of this requirement.

*Response:* A contingency plan is the only way to protect the availability, integrity, and security of data during unexpected negative events. Data are often most exposed in these events, since the usual security measures may be disabled, ignored, or not observed.

Each entity needs to determine its own risk in the event of an emergency that would result in a loss of operations. A contingency plan may involve highly complex processes in one processing site, or simple manual processes in another. The contents of any given contingency plan will depend upon the nature and configuration of the entity devising it.

While the contingency plan standard must be met, we agree that the proposed

testing and revision implementation feature should be an addressable implementation specification in this final rule. Dependent upon the size, configuration, and environment of a given covered entity, the entity should decide if testing and revision of all parts of a contingency plan should be done or if there are more reasonable alternatives. The same is true for the proposed applications and data criticality analysis implementation feature. We have revised the final rule to reflect this approach.

b. *Comment:* One commenter believed that adhering to this requirement could prove burdensome. Another stated that testing of certain parts of a contingency plan would be burdensome, and even infeasible, for smaller entities.

*Response:* Without contingency planning, a covered entity has no assurance that its critical data could survive an emergency situation. Recent events, such as September 11, 2001, illustrate the importance of such planning. Contingency planning will be scalable based upon, among other factors, office configuration, and risk assessment. However, in response to the scalability issue raised by the commenter, we have made the testing and revision implementation specification addressable (see § 164.308(a)(7)(ii)).

c. *Comment:* Two commenters considered a 2-year implementation time frame for this requirement inadequate for large health plans. Another commenter stated that implementation of measures against natural disaster would be too big an issue for this regulation.

*Response:* The statute sets forth the compliance dates for the initial standards. The statute requires that compliance with initial standards is not later than 2 years after adoption of the standards for all covered entities except small health plans for which the compliance date is not later than 3 years after adoption.

The final rule calls for covered entities to consider how natural disasters could damage systems that contain electronic protected health information and develop policies and procedures for responding to such situations. We consider this to be a reasonable precautionary step to take since in many cases the risk would be deemed to be low.

d. *Comment:* A commenter requested clarification of the term "Emergency mode" with regard to the proposed "Emergency mode operation plan" implementation feature.

*Response:* We have clarified the "Emergency mode operations plan" to

show that it only involves those critical business processes that must occur to protect the security of electronic protected health information during and immediately after a crisis situation.

#### 8. Evaluation (§ 164.308(a)(8))

We proposed that certification would be required and could be performed internally or by an external accrediting agency. We solicited input on appropriate mechanisms to permit an independent assessment of compliance. We were particularly interested in input from those engaging in health care electronic data interchange (EDI), as well as independent certification and auditing organizations addressing issues of documentary evidence of steps taken for compliance; need for, or desirability of, independent verification, validation, and testing of system changes; and certifications required for off-the-shelf products used to meet the requirements of this regulation. We also solicited comments on the extent to which obtaining external certification would create an undue burden on small or rural providers.

In this final rule, we require covered entities to periodically conduct an evaluation of their security safeguards to demonstrate and document their compliance with the entity's security policy and the requirements of this subpart. Covered entities must assess the need for a new evaluation based on changes to their security environment since their last evaluation, for example, new technology adopted or responses to newly recognized risks to the security of their information.

a. *Comment:* We received several comments that certification should be performed externally. A larger group of commenters preferred self-certification. The majority of the comments, however, were to the effect that external certification should be encouraged but not mandated.

A number of commenters thought that mandating external certification would create an undue financial burden, regardless of the size of the entity being certified. One commenter stated that external certification would not place an undue burden on a small or rural provider.

*Response:* Evaluation by an external entity is a business decision to be left to each covered entity. Evaluation is required under § 164.308(a)(8), but a covered entity may comply with this standard either by using its own workforce or an external accreditation agency, which would be acting as a business associate. External evaluation may be too costly an option for small entities.

b. *Comment:* Several commenters stated that the certification should cover all components of the proposed rule, not just the information systems.

*Response:* We agree. We have revised this section to reflect that evaluation would be both technical and nontechnical components of security.

c. *Comment:* A number of commenters expressed a desire for the creation of certification guides or models to complement the rule.

*Response:* We agree that creation of compliance guidelines or models for different business environments would help in the implementation and evaluation of HIPAA security requirements and we encourage professional associations and others to do so. We may develop technical assistance materials, but do not intend to create certification criteria because we do not have the resources to address the large number of different business environments.

d. *Comment:* Some commenters asked how certification is possible without specifying the level of risk that is permissible.

*Response:* The level of risk that is permissible is specified by § 164.306(a). How such risk is managed will be determined by a covered entity through its security risk analysis and the risk mitigation activities it implements in order to ensure that the level of security required by § 164.306 is provided.

e. *Comment:* Several commenters requested creation of a list of Federally “certified” security software and off-the-shelf products. Several others stated that this request was not feasible. Regarding certification of off-the-shelf products, one commenter thought this should be encouraged, but not mandated; several thought this would be an impractical endeavor.

*Response:* While we will not assume the task of certifying software and off-the-shelf products for the reason described above, we have noted with interest that other Government agencies such as the National Institute of Standards and Technology (NIST) are working towards that end. The health care industry is encouraged to monitor the activity of NIST and provide comments and suggestions when requested (see <http://www.niap.nist.gov>).

f. *Comment:* One commenter stated, “With HCFA’s publishing of these HIPAA standards, and their desire to retain the final responsibility for determining violations and imposing penalties of the statute, it also seems appropriate for HCFA to also provide certifying services to ensure security compliance.”

*Response:* In view of the enormous number and variety of covered entities, we believe that evaluation can best be handled through the marketplace, which can develop more usable and targeted evaluation instruments and processes.

#### 8. Business Associate Contracts or Other Arrangements (§ 164.308(b)(1))

In the proposed rule § 142.308(a)(2) “Chain of trust” requirement, we proposed that covered entities be required to enter into a chain of trust partner agreement with their business partners, in which the partners would agree to electronically exchange data and protect the integrity, confidentiality, and availability of the data exchanged. This standard has been modified from the proposed requirement to reflect, in § 164.308(b)(1) “Business associate contracts and other arrangements,” the business associate structure put in place by the Privacy Rule.

In this final rule, covered entities must enter into a contract or other arrangement with persons that meet the definition of business associate in § 160.103. The covered entity must obtain satisfactory assurances from the business associate that it will appropriately safeguard the information in accordance with these standards (see § 164.314(a)(1)).

The comments received on the proposed chain of trust partner agreements are discussed in section 2 “Business associate contracts and other arrangements” of the discussion of § 164.314 below.

#### 9. Proposed Requirements Not Adopted in This Final Rule

##### a. Security Configuration Management

We proposed that an organization would be required to implement measures, practices, and procedures regarding security configuration management. They would be coordinated and integrated with other system configuration management practices for the security of information systems. These would include documentation, hardware and/or software installation and maintenance review and testing for security features, inventory procedures, security testing, and virus checking.

*Comment:* Several commenters asked that the entire requirement be deleted. Several others asked that the inventory and virus checking implementation features be removed as they believe those features are not germane to security configuration management. A number of commenters requested that

security testing be deleted because this implementation feature is too detailed, unreasonable, impractical, and beyond the scope of the legislation. Others stated that the testing would be very complex and expensive. Others wanted more clarification of what we intend by security testing, and how much would be enough. A number of commenters asked that all of the implementation features be deleted. Others asked that the implementation features be made optional. Several commenters wanted to know the scope of organizational integration required. Several others asked if what we meant by Security Configuration Management was change or version control.

*Response:* Upon review, this requirement appears unnecessary because it is redundant of other requirements we are adopting in this rule. A covered entity will have addressed the activities described by the features under this proposed requirement by virtue of having implemented the risk analysis, risk management measures, sanction policies, and information systems criticality review called for under the security management process. The proposed documentation implementation feature has been made a separate standard (see § 164.316). As a result, the Security Configuration Management requirement is not adopted in this final rule.

##### b. Formal Mechanism for Processing Records

The proposed rule proposed requiring a formal mechanism for processing records, and documented policies and procedures for the routine and nonroutine receipt, manipulation, storage, dissemination, transmission, and/or disposal of health information. This requirement has not been adopted in the final rule.

*Comment:* Several commenters thought this requirement concerned the regulation of formal procedures for how an entity does business and stated that such procedures should not be regulated. Others asked for additional clarification of what is meant by this requirement. One commenter thought the requirement too ambiguous and asked for clarification as to whether we meant such things as “the proper handling of storage media, databases, transmissions,” or “the clinical realm of processes.”

Two commenters asked how extensive this requirement would be and whether systems’ user manuals and policies and procedures for handling health information would suffice and what level of detail would be expected.

Several thought this requirement could result in a significant resource and monetary burden to develop and maintain formal procedures. Two asked for an explanation of the benefit to be derived from this requirement.

One asked that covered entities be required to document processes that create a security risk only and suggested that a risk assessment would determine the need for this documentation.

*Response:* We agree with the commenters that the standard is ambiguous, and upon review, is unnecessary because the remaining standards, for example, device and media controls, provide adequate safeguards. Accordingly, this requirement is not adopted in this final rule.

#### F. Physical Safeguards (§ 164.310)

We proposed requirements and implementation features for documented physical safeguards to guard data integrity, confidentiality, and availability. We proposed to require safeguards in the following areas: Assigned security responsibility; media controls; physical access controls; policies and guidelines on workstation use; a secure workstation location; and security awareness training. A number of specific implementation features were proposed under the media controls and physical access controls requirements.

In § 164.310 of this final rule, most of the proposed implementation features are adopted as addressable implementation specifications. The proposed requirements for the assigned security responsibility and security awareness training requirements are relocated in § 164.308.

##### 1. General Comments

a. *Comment:* Several commenters made suggestions to modify the language to more clearly describe “Physical safeguards.”

*Response:* In response to comments, we have revised the definition of “Physical safeguards” to read as follows: “Physical safeguards are security measures to protect a covered entity’s electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.”

b. *Comment:* One commenter was concerned that electronic security systems could not be used in lieu of physical security systems.

*Response:* This final rule does not preclude the use of electronic security systems in lieu of, or in combination with, physical security systems to meet a “Physical safeguard” standard.

##### 2. Facility Access Controls (§ 164.310(a)(1))

We proposed, under the “Physical access controls” requirement, formal, documented policies and procedures for limiting physical access to an entity while ensuring that properly authorized access is allowed. These controls would include the following implementation features: disaster recovery, emergency mode operation, equipment control (into and out of site), a facility security plan, procedures for verifying access authorizations before physical access, maintenance records, need-to-know procedures for personnel access, sign-in for visitors and escort, if appropriate, and testing and revision.

In § 164.310(a)(2) below, we combine and restate these as addressable implementation specifications. These are contingency operations, facility security plan, access control and validation procedures, and maintenance records.

a. *Comment:* Many commenters were concerned because the proposed language would require implementation of all physical access control features. Other commenters were concerned that the language did not allow entities to use the results of their risk assessment and risk management process to arrive at the appropriate solutions for them.

*Response:* We agree that implementation of all implementation specifications may not be appropriate in all situations. While the facility access controls standard must be met, we agree that the implementation specifications should not be required in all circumstances, but should be addressable. In this final rule, all four implementation specifications are addressable.

We have also determined, based on “level of detail” comments requesting consolidation of the list of implementation features, that the proposed implementation feature “Equipment control (into and out of site)” was redundant. “Equipment control” is already covered under the “Device and media controls” standard at § 164.310(d)(1). Accordingly, we have eliminated it as a separate implementation specification.

b. *Comment:* One commenter raised the issue of a potential conflict of authority between those having access to the data and those responsible for checking and maintaining access controls.

*Response:* Any potential conflicts should be identified, addressed, and resolved in the policies and procedures developed according to the standards under § 164.308.

c. *Comment:* Several commenters questioned whether “Physical Access Controls” was a descriptive phrase to describe a technology to be used, or whether the phrase referred to a facility.

*Response:* We agree that the term “Physical” may be misleading; to remove any confusion, the requirement is reflected in this final rule as a standard titled “Facility access controls.” We believe this is a more precise term to describe that the standard, and its associated implementation specifications, is applicable to an entity’s business location or locations.

d. *Comment:* Several commenters requested that the disaster recovery and emergency mode operations features be moved to “Administrative safeguards.” Other commenters recommended that disaster recovery and emergency mode operations should be replaced by, and included in, a “Contingency Operations” implementation feature.

*Response:* The “Administrative safeguards” section addresses the contingency planning that must be done to contend with emergency situations. The placement of the disaster recovery and emergency mode operations implementation specifications in the “Physical safeguards” section is also appropriate, however, because “Physical safeguards” defines the physical operations (processes) that provide access to the facility to implement the associated plans, developed under § 164.308. We agree, however, that the term “contingency operations” better describes, and would include, disaster recovery and emergency mode operations, and have modified the regulation text accordingly (see § 164.310(a)(1)).

e. *Comment:* Commenters were concerned about having to address in their facility security plan the exterior/interior security of a building when they are one of many occupants rather than the sole occupant. Additional commenters were concerned that the responsibility for physical security of the building could not be delegated to a third party when the covered entity shares the building with other offices.

*Response:* The facility security plan is an addressable implementation specification. However, the covered entity retains responsibility for considering facility security even where it shares space within a building with other organizations. Facility security measures taken by a third party must be considered and documented in the covered entity’s facility security plan, when appropriate.



### 3. Workstation Use (§ 164.310(b))

We proposed policy and guidelines on workstation use that included documented instructions/procedures delineating the proper functions to be performed and the manner in which those functions are to be performed (for example, logging off before leaving a workstation unattended) to maximize the security of health information. In this final rule, we adopt this standard.

*Comment:* One commenter was concerned most people may be misled by the use of “terminal” as an example in the definition of workstation. The concern was that the standard only addresses “fixed location devices,” while in many instances the workstation has become a laptop computer.

*Response:* For clarity, we have added the definition of “workstation” to § 164.304 and deleted the word “terminal” from the description of workstation use in § 164.310(b).

### 4. Workstation Security (§ 164.310(c))

We proposed that each organization would be required to put in place physical safeguards to restrict access to information. In this final rule, we retain the general requirement for a secure workstation.

*Comment:* Comments were directed toward the example profiled in the definition of a secure workstation location. It was believed that what constitutes a secure workstation location must be dependent upon the entity’s risk management process.

*Response:* We agree that what constitutes an appropriate solution to a covered entity’s workstation security issues is dependent on the entity’s risk analysis and risk management process. Because many commenters incorrectly interpreted the examples as the required and only solution for securing the workstation location, we have modified the regulations text description to generalize the requirement (see § 164.310(c)). Also, for clarity, the title “Secure workstation location” has been changed to “Workstation security” (see also the definition of “Workstation” at § 164.304).

### 5. Device and Media Controls (§ 164.310(d)(1))

We proposed that covered entities have media controls in the form of formal, documented policies and procedures that govern the receipt and removal of hardware and/or software (for example, diskettes and tapes) into and out of a facility. Implementation features would have included “Access control,” “Accountability” (tracking mechanism), “Data backup,” “Data storage,” and “Disposal.”

In this final rule, we adopt most of these provisions as addressable implementation specifications and add a specification for media re-use. We change the name from “Media controls” to “Device and media controls” to more clearly reflect that this standard concerns hardware as well as electronic media. The proposed “Access control” implementation feature has been removed, as it is addressed as part of other standards (see section III.C.12.c of this preamble).

a. *Comment:* One commenter was concerned about the exclusion of removable media devices from examples of physical types of hardware and/or software.

*Response:* The media examples used were not intended to represent all possible physical types of hardware and/or software. Removable media devices, although not specifically listed, are not intended to be excluded.

b. *Comment:* Comments were made that the issue of equipment re-use or recycling of media containing mass storage was not addressed in “Media controls.”

*Response:* We agree that equipment re-use or recycling should be addressed, since this equipment may contain electronic protected health information. The “Device and media controls” standard is accordingly expanded to include a required implementation specification that addresses the re-use of media (see § 164.310(d)(2)(ii)).

c. *Comment:* Several commenters asked for a definition of the term “facility,” as used in the proposed “Media controls” requirement description. Commenters were unclear whether we were talking about a corporate entity or the physical plant.

*Response:* The term “facility” refers to the physical premises and the interior and exterior of a building(s). We have added this definition to § 164.304.

d. *Comment:* Several commenters believe the “Media controls” implementation features are too onerous and should be deleted.

*Response:* While the “Device and media controls” standard must be met, we believe, based upon further review, that implementation of all specifications would not be necessary in every situation, and might even be counter-productive in some situations. For example, small providers would be unlikely to be involved in large-scale moves of equipment that would require systematic tracking, unlike, for example, large health care providers or health plans. We have, therefore, reclassified the “Accountability and data backup” implementation specification as

addressable to provide more flexibility in meeting the standard.

e. *Comment:* One commenter was concerned about the accountability impact of audit trails on system resources and the pace of system services.

*Response:* The proposed audit trail implementation feature appears as the addressable “Accountability” implementation specification. The name change better reflects the purpose and intended scope of the implementation specification. This implementation specification does not address audit trails within systems and/or software. Rather it requires a record of the actions of a person relative to the receipt and removal of hardware and/or software into and out of a facility that are traceable to that person. The impact of maintaining accountability on system resources and services will depend upon the complexity of the mechanism to establish accountability. For example, the appropriate mechanism for a given entity may be manual, such as receipt and removal restricted to specific persons, with logs kept. Maintaining accountability in such a fashion should have a minimal, if any, effect on system resources and services.

f. *Comment:* A commenter was concerned about the resource expenditure (system and fiscal) for total e-mail backup and wanted a clarification of the extensiveness of data backup.

*Response:* The data an entity needs to backup, and which operations should be used to carry out the backup, should be determined by the entity’s risk analysis and risk management process. The data backup plan, which is part of the required contingency plan (see § 164.308(a)(7)(ii)(A)), should define exactly what information is needed to be retrievable to allow the entity to continue business “as usual” in the face of damage or destruction of data, hardware, or software. The extent to which e-mail backup would be needed would be determined through that analysis.

### G. Technical Safeguards (§ 164.312)

We proposed five technical security services requirements with supporting implementation features: Access control; Audit controls; Authorization control; Data authentication; and Entity authentication. We also proposed specific technical security mechanisms for data transmitted over a communications network, Communications/network controls with supporting implementation features; Integrity controls; Message authentication; Access controls;



Encryption; Alarm; Audit trails; Entity authentication; and Event reporting.

In this final rule, we consolidate these provisions into § 164.312. That section now includes standards regarding access controls, audit controls, integrity (previously titled data authentication), person or entity authentication, and transmission security. As discussed below, while certain implementation specifications are required, many of the proposed security implementation features are now addressable implementation specifications. The function of authorization control has been incorporated into the information access management standard under § 164.308, Administrative safeguards.

#### 1. Access Control (§ 164.312(a)(1))

In the proposed rule, we proposed to require that the access controls requirement include features for emergency access procedures and provisions for context-based, role-based, and/or user-based access; we also proposed the optional use of encryption as a means of providing access control. In this final rule, we require unique user identification and provision for emergency access procedures, and retain encryption as an addressable implementation specification. We also make "Automatic logoff" an addressable implementation specification. "Automatic logoff" and "Unique user identification" were formerly implementation features under the proposed "Entity authentication" (see § 164.312(d)).

a. *Comment:* Some commenters believe that in specifying "Context," "Role," and "User" based controls, use of other controls would effectively be excluded, for example, "Partition rule-based access controls," and the development of new access control technology.

*Response:* We agree with the commenters that other types of access controls should be allowed. There was no intent to limit the implementation features to the named technologies and this final rule has been reworded to make it clear that use of any appropriate access control mechanism is allowed. Proposed implementation features titled "Context-based access," "Role-based access," and "User-based access" have been deleted and the access control standard at § 164.312(a)(1) states the general requirement.

b. *Comment:* A large number of comments were received objecting to the identification of "Automatic logoff" as a mandatory implementation feature. Generally the comments asked that we not be so specific and allow other forms of inactivity lockout, and that this type

of feature be made optional, based more on the particular configuration in use and a risk assessment/analysis.

*Response:* We agree with the comments that mandating an automatic logoff is too specific. This final rule has been written to clarify that the proposed implementation feature of automatic logoff now appears as an addressable access control implementation specification and also permits the use of an equivalent measure.

c. *Comment:* We received comments asking that encryption be deleted as an implementation feature and stating that encryption is not required for "data at rest."

*Response:* The use of file encryption is an acceptable method of denying access to information in that file. Encryption provides confidentiality, which is a form of control. The use of encryption, for the purpose of access control of data at rest, should be based upon an entity's risk analysis. Therefore, encryption has been adopted as an addressable implementation specification in this final rule.

d. *Comment:* We received one comment stating that the proposed implementation feature "Procedure for emergency access," is not access control and recommending that emergency access be made a separate requirement.

*Response:* We believe that emergency access is a necessary part of access controls and, therefore, is properly a required implementation specification of the "Access controls" standard. Access controls will still be necessary under emergency conditions, although they may be very different from those used in normal operational circumstances. For example, in a situation when normal environmental systems, including electrical power, have been severely damaged or rendered inoperative due to a natural or man-made disaster, procedures should be established beforehand to provide guidance on possible ways to gain access to needed electronic protected health information.

#### 2. Audit Controls (§ 164.312(b))

We proposed that audit control mechanisms be put in place to record and examine system activity. We adopt this requirement in this final rule.

a. *Comment:* We received a comment stating that "Audit controls" should be an implementation feature rather than the standard, and suggesting that we change the title of the standard to "Accountability," and provide additional detail to the audit control implementation feature.

*Response:* We do not adopt the term "Accountability" in this final rule

because it is not descriptive of the requirement, which is to have the capability to record and examine system activity. We believe that it is appropriate to specify audit controls as a type of technical safeguard. Entities have flexibility to implement the standard in a manner appropriate to their needs as deemed necessary by their own risk analyses. For example, see NIST Special Publication 800-14, *Generally Accepted Principles and Practices for Securing Information Technology Systems* and NIST Special Publication 800-33, *Underlying Technical Models for Information Technology Security*.

b. *Comment:* One commenter recommended that this final rule state that audit control mechanisms should be implemented based on the findings of an entity's risk assessment and risk analysis. The commenter asserted that audit control mechanisms should be utilized only when appropriate and necessary and should not adversely affect system performance.

*Response:* We support the use of a risk assessment and risk analysis to determine how intensive any audit control function should be. We believe that the audit control requirement should remain mandatory, however, since it provides a means to assess activities regarding the electronic protected health information in an entity's care.

c. *Comment:* One commenter was concerned about the interplay of State and Federal requirements for auditing of privacy data and requested additional guidance on the interplay of privacy rights, laws, and the expectation for audits under the rule.

*Response:* In general, the security standards will supercede any contrary provision of State law. Security standards in this final rule establish a minimum level of security that covered entities must meet. We note that covered entities may be required by other Federal law to adhere to additional, or more stringent security measures. Section 1178(a)(2) of the statute provides several exceptions to this general rule. With regard to protected health information, the preemption of State laws and the relationship of the Privacy Rule to other Federal laws is discussed in the Privacy Rule beginning at 65 FR 82480; the preemption provisions of the rule are set out at 45 CFR part 160, subpart B.

It should be noted that although the Privacy Rule does not incorporate a requirement for an "audit trail" function, it does call for providing an accounting of certain disclosures of protected health information to an

individual upon request. There has been a tendency to assume that this Privacy Rule requirement would be satisfied via some sort of process involving audit trails. We caution against assuming that the Security Rule's requirement for an audit capability will satisfy the Privacy Rule's requirement regarding accounting for disclosures of protected health information. The two rules cover overlapping, but not identical information. Further, audit trails are typically used to record uses within an electronic information system, while the Privacy Rule requirement for accounting applies to certain disclosures outside of the covered entity (for example, to public health authorities).

### 3. Integrity (§ 164.312(c)(1))

We proposed under the "Data authentication" requirement, that each organization be required to corroborate that data in its possession have not been altered or destroyed in an unauthorized manner and provided examples of mechanisms that could be used to accomplish this task. We adopt the proposed requirement for data authentication in the final rule as an addressable implementation specification "Mechanism to authenticate data," under the "Integrity" standard.

*a. Comment:* We received a large number of comments requesting clarification of the "Data authentication" requirement. Many of these comments suggested that the requirement be called "Data integrity" instead of "Data authentication." Others asked for guidance regarding just what "data" must be authenticated. A significant number of commenters indicated that this requirement would put an extraordinary burden on large segments of the health care industry, particularly when legacy systems are in use. Requests were received to make this an "optional" requirement, based on an entity's risk assessment and analysis.

*Response:* We adopt the suggested "integrity" terminology because it more clearly describes the intent of the standard. We retain the meaning of the term "Data authentication" under the addressable implementation specification "Mechanism to authenticate data," and provide an example of a potential means to achieve data integrity.

Error-correcting memory and magnetic disc storage are examples of the built-in data authentication mechanisms that are ubiquitous in hardware and operating systems today. The risk analysis process will address what data must be authenticated and

should provide answers appropriate to the different situations faced by the various health care entities implementing this regulation.

Further, we believe that this standard will not prove difficult to implement, since there are numerous techniques available, such as processes that employ digital signature or check sum technology to accomplish the task.

*b. Comment:* We received numerous comments suggesting that "Double keying" be deleted as a viable "Data authentication" mechanism, since this practice was generally associated with the use of punched cards.

*Response:* We agree that the process of "Double keying" is outdated. This final rule omits any reference to "Double keying."

### 4. Person or Entity Authentication (§ 164.312(d))

We proposed that an organization implement the requirement for "Entity authentication", the corroboration that an entity is who it claims to be. "Automatic logoff" and "Unique user identification" were specified as mandatory features, and were to be coupled with at least one of the following features: (1) A "biometric" identification system; (2) a "password" system; (3) a "personal identification number"; and (4) "telephone callback," or a "token" system that uses a physical device for user identification.

In this final rule, we provide a general requirement for person or entity authentication without the specifics of the proposed rule.

*Comment:* We received comments from a number of organizations requesting that the implementation features for entity authentication be either deleted in their entirety or at least be made optional. On the other hand, comments were received requesting that the use of digital signatures and soft tokens be added to the list of implementation features.

*Response:* We agree with the commenters that many different mechanisms may be used to authenticate entities, and this final rule now reflects this fact by not incorporating a list of implementation specifications, in order to allow covered entities to use whatever is reasonable and appropriate. "Digital signatures" and "soft tokens" may be used, as well as many other mechanisms, to implement this standard.

The proposed mandatory implementation feature, "Unique user identification," has been moved from this standard and is now a required implementation specification under "Access control" at § 164.312(a)(1).

"Automatic logoff" has also been moved from this standard to the "Access control" standard and is now an addressable implementation specification.

### 5. Transmission Security (§ 164.312(e)(1))

Under "Technical Security Mechanisms to Guard Against Unauthorized Access to Data that is Transmitted Over a Communications Network," we proposed that "Communications/network controls" be required to protect the security of health information when being transmitted electronically from one point to another over open networks, along with a combination of mandatory and optional implementation features. We proposed that some form of encryption must be employed on "open" networks such as the Internet or dial-up lines.

In this final rule, we adopt integrity controls and encryption, as addressable implementation specifications.

*a. Comment:* We received a number of comments asking for overall clarification as well as a definition of terms used in this section. A definition for the term "open networks" was the most requested action, but there was a general expression of dislike for the manner in which we approached this section, with some comments suggesting that the entire section be rewritten. A significant number of comments were received on the question of encryption requirements when dial-up lines were to be employed as a means of connectivity. The overwhelming majority strongly urged that encryption not be mandatory when using any transmission media other than the Internet, but rather be considered optional based on individual entity risk assessment/analysis. Many comments noted that there are very few known breaches of security over dial-up lines and that nonjudicious use of encryption can adversely affect processing times and become both financially and technically burdensome. Only one commenter suggested that "most" external traffic should be encrypted.

*Response:* In general, we agree with the commenters who asked for clarification and revision. This final rule has been significantly revised to reflect a much simpler and more direct requirement. The term "Communications/network controls" has been replaced with "Transmission security" to better reflect the requirement that, when electronic protected health information is transmitted from one point to another, it must be protected in a manner commensurate with the associated risk.

We agree with the commenters that switched, point-to-point connections, for example, dial-up lines, have a very small probability of interception.

Thus, we agree that encryption should not be a mandatory requirement for transmission over dial-up lines. We also agree with commenters who mentioned the financial and technical burdens associated with the employment of encryption tools. Particularly when considering situations faced by small and rural providers, it became clear that there is not yet available a simple and interoperable solution to encrypting e-mail communications with patients. As a result, we decided to make the use of encryption in the transmission process an addressable implementation specification. Covered entities are encouraged, however, to consider use of encryption technology for transmitting electronic protected health information, particularly over the internet.

As business practices and technology change, there may arise situations where electronic protected health information being transmitted from a covered entity would be at significant risk of being accessed by unauthorized entities. Where risk analysis showed such risk to be significant, we would expect covered entities to encrypt those transmissions, if appropriate, under the addressable implementation specification for encryption.

We do not use the term "open network" in this final rule because its meaning is too broad. We include as an addressable implementation specification the requirement that transmissions be encrypted when appropriate based on the entity's risk analysis.

*b. Comment:* We received comments requesting that the implementation features be deleted or made optional. Three commenters asked that the requirement for an alarm be deleted.

*Response:* This final rule has been revised to reflect deletion of the following implementation features: (1) The alarm capability; (2) audit trail; (3) entity authentication; and (4) event reporting. These features were associated with a proposed requirement for "Communications/network controls" and have been deleted since they are normally incorporated by telecommunications providers as part of network management and control functions that are included with the provision of network services. A health care entity would not expect to be responsible for these technical telecommunications features. "Access controls" has also been deleted from the implementation features since the consideration of the use of encryption

will satisfy the intent of this feature. We retain as addressable implementation specifications two features: (1) "Integrity controls" and "encryption". "Message authentication" has been deleted as an implementation feature because the use of data authentication codes (called for in the "integrity controls" implementation specification) satisfies the intent of "Message authentication."

*c. Comment:* A number of comments were received asking that this final rule establish a specific (or at least a minimum) cryptographic algorithm strength. Others recommended that the rule not specify an encryption strength since technology is changing so rapidly. Several commenters requested guidelines and minimum encryption standards for the Internet. Another stated that, since an example was included (small or rural providers for example), the government should feel free to name a specific encryption package. One commenter stated that the requirement for encryption on the Internet should reference the "CMS Internet Security Policy."

*Response:* We remain committed to the principle of technology neutrality and agree with the comment that rapidly changing technology makes it impractical and inappropriate to name a specific technology. Consistent with this principle, specification of an algorithm strength or specific products would be inappropriate. Moreover, rapid advances in the success of "brute force" cryptanalysis techniques suggest that any minimum specification would soon be outmoded. We maintain that it is much more appropriate for this final rule to state a general requirement for encryption protection when necessary and depend on covered entities to specify technical details, such as algorithm types and strength. Because "CMS Internet Security Policy" is the policy of a single organization and applies only to information sent to CMS, and not between all covered entities, we have not referred to it here.

*d. Comment:* The proposed definition of "Integrity controls" generated comments that asked that the word "validity" be changed to "Integrity." Commenters were concerned about the ability of an entity to ensure that information was "valid."

*Response:* We agree with the commenters about the meaning of the word "validity" in the context of the proposed definition of "Integrity controls." We have named "integrity controls" as an implementation specification in this final rule to require mechanisms to ensure that electronically transmitted information is

not improperly modified without detection (see § 164.312(c)(1)).

*e. Comment:* Three commenters asked for clarification and guidance regarding the unsolicited electronic receipt of health information in an unsecured manner, for example, when the information was submitted by a patient via e-mail over the Internet. Commenters asked for guidance as to what was their obligation to protect data received in this manner.

*Response:* The manner in which electronic protected health information is received by a covered entity does not affect the requirement that security protection must subsequently be afforded to that information by the covered entity once that information is in possession of the covered entity.

## 6. Proposed Requirements Not Adopted in This Final Rule

### a. Authorization Control

We proposed, under "Technical Security Services to Guard Data Integrity, Confidentiality, and Availability," that a mechanism be required for obtaining consent for the use and disclosure of health information using either "Role-based access" or "User-based access" controls. In this final rule, we do not adopt this requirement.

*Comment:* We received a large number of comments regarding use of the word "consent." It was pointed out that this could be construed to mean patient consent to the use or disclosure of patient information, which would make this a privacy issue, rather than one of security. Other comments suggested deletion of the requirement in its entirety. We received a comment asking for clarification about the distinction between "Access control" and "Authorizations."

*Response:* These requirements were intended to address authorization of workforce members and others for the use and disclosure of health information, not patient consent. Upon reviewing the differences between "Access control" and "Authorization control," we found it to be unnecessary to retain "Authorization control" as a separate requirement. Both the access control and the authorization control proposed requirements involved implementation of types of automated access controls, that is, role-based access and user-based access. It can be argued that the process of managing access involves allowing and restricting access to those individuals that have been authorized to access the data. The intent of the proposed authorization control implementation feature is now

incorporated in the access authorization implementation specification under the information access management standard in § 164.308(a)(4). Under the information access management standard, a covered entity must implement, if appropriate and reasonable to its situation, policies and procedures first to authorize a person to access electronic protected health information and then to actually establish such access. These policies and procedures will enable entities to follow the Privacy Rule minimum necessary requirements, which provide when persons should have access to information.

#### *H. Organizational Requirements* (§ 164.314)

We proposed that each health care clearinghouse must comply with the security standards to ensure all health information and activities are protected from unauthorized access. If the clearinghouse is part of a larger organization, then unauthorized access by the larger organization must be prevented. We also proposed that parties processing data through a third party would be required to enter into a chain of trust partner agreement, a contract in which the parties agree to electronically exchange data and to protect the transmitted data in accordance with the security standards.

In this final rule, we have adopted the concepts of hybrid and affiliated entities, as previously defined in § 164.504, and now defined in § 164.103, and business associates as defined in § 160.103, to be consistent with the Privacy Rule. General organizational requirements related to affiliated covered entities and hybrid entities are now contained in a new § 164.105. The proposed chain of trust partner agreement has been replaced by the standards for business associate contracts or other arrangements and the standards for group health plans. Consistent with the statute and the policy of the Privacy Rule, this final rule does not require noncovered entities to comply with the security standards.

##### 1. Health Care Clearinghouses

The proposed rule proposed that if a health care clearinghouse were part of a larger organization, it would be required to ensure that all health information pertaining to an individual is protected from unauthorized access by the larger organization; this statement closely tracked the statutory language in section 1173(d)(1)(B) of the Act. Since the point of the statutory language is to ensure that health care information in the possession of a health care

clearinghouse is not inappropriately accessed by the larger organization of which it is a part, this final rule implements the statutory language through the information access management provision of § 164.308(a)(4)(ii)(A).

The final rule, at § 164.105, makes the health care component and affiliated entity standards of the Privacy Rule applicable to the security standards. Therefore, we have not changed those standards substantively. In pertaining to the Privacy Rule, we have simply moved them to a new location in part 164. Any differences between § 164.105 and § 164.504(a) through (d) reflects the addition of requirements specific to the security standards.

The health care component approach was developed in response to extensive comment received principally on the Privacy Rule. See 65 FR 82502 through 82503 and 82637 through 82640 for a discussion of the policy concerns underlying the health care component approach. Since the security standards are intended to support the protection of electronic information protected by the Privacy Rule, it makes sense to incorporate organizational requirements that parallel those required of covered entities by the Privacy Rule. This policy will also minimize the burden of complying with both rules.

a. *Comment:* Relative to the following preamble statement (63 FR 43258): “If the clearinghouse is part of a larger organization, then security must be imposed to prevent unauthorized access by the larger organization.” One commenter asked what is considered to be “the larger organization.” For example, if a clearinghouse function occurs in a department of a larger business entity, will the regulation cover all internal electronic communication, such as e-mail, within the larger business and all external electronic communication, such as e-mail with its owners?

*Response:* The “larger organization” is the overall business entity that a clearinghouse would be part of. Under the Security Rule, the larger organization must assure that the health care clearinghouse function has instituted measures to ensure only that electronic protected health information that it processes is not improperly accessed by unauthorized persons or other entities, including the larger organization. Internal electronic communication within the larger organization will not be covered by the rule if it does not involve the clearinghouse, assuming that it has designated health care components, of which the health care clearinghouse is

one. External communication must be protected as sent by the clearinghouse, but need not be protected once received.

b. *Comment:* One commenter asked that the first sentence in § 142.306(b) of the proposed rule, “If a health care clearinghouse is part of a larger organization, it must assure all health information is protected from unauthorized access by the larger organization” be expanded to read, “If a health care clearinghouse or any other health care entity is part of a larger organization . . .”

*Response:* The Act specifically provides, at section 1173(d)(1)(B), that the Secretary must adopt standards to ensure that a health care clearinghouse, if part of a larger organization, has policies and security procedures to protect information from unauthorized access by the larger organization.

Health care providers and health plans are often part of larger organizations that are not themselves health care providers or health plans. The security measures implemented by health plans and covered health care providers should protect electronic protected health information in circumstances such as the one identified by the commenter. Therefore, we agree with the comment that the requirement should be expanded as suggested by the commenter. In this final rule, those components of a hybrid entity that are designated as health care components must comply with the security standards and protect against unauthorized access with respect to the other components of the larger entity in the same way as they must deal with separate entities.

##### 2. Business Associate Contracts and Other Arrangements

We proposed that parties processing data through a third party would be required to enter into a chain of trust partner agreement, a contract in which the parties agree to electronically exchange data and to protect the transmitted data. This final rule narrows the scope of agreements required. It essentially tracks the provisions in § 164.502(e) and § 164.504(e) of the Privacy Rule, although appropriate modifications have been made in this rule to the required elements of the contract.

In this final rule, a contract between a covered entity and a business associate must provide that the business associate must—(1) implement safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates,

receives, maintains, or transmits on behalf of the covered entity; (2) ensure that any agent, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate safeguards; (3) report to the covered entity any security incident of which it becomes aware; (4) make its policies and procedures, and documentation required by this subpart relating to such safeguards, available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and (5) authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract.

When a covered entity and its business associate are both governmental entities, an "other arrangement" is sufficient. The covered entity is in compliance with this standard if it enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of the above-described business associate contract. However, the covered entity may omit from this memorandum the termination authorization required by the business associate contract provisions if this authorization is inconsistent with the statutory obligations of the covered entity or its business associate. If other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of the above-described business associate contract, a contract or agreement is not required. If a covered entity enters into other arrangements with another governmental entity that is a business associate, such arrangements may omit provisions equivalent to the termination authorization required by the business associate contract, if inconsistent with the statutory obligation of the covered entity or its business associate.

If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, the covered entity may permit the business associate to receive, create, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of the above-described business associate contract, *provided that* the covered entity attempts in good faith to obtain satisfactory assurances as required by the above described

business associate contract and documents the attempt and the reasons that these assurances cannot be obtained.

We have added a standard for group health plans that parallels the provisions of the Privacy Rule. It became apparent during the course of the security and privacy rulemaking that our original chain of trust approach was both overly broad in scope and failed to address appropriately the circumstances of certain covered entities, particularly the ERISA group health plans. These latter considerations and the solutions arrived at in the Privacy Rule are described in detail in the Privacy Rule at 65 FR 82507 through 82509. Because the purpose of the security standards is in part to reinforce privacy protections, it makes sense to align the organizational policies of the two rules. This decision should also make compliance less burdensome for covered entities than would a decision to have different organizational requirements for the two sets of rules.

Thus, we have added at § 164.314(b) a standard for group health plan that tracks the standard at § 164.504(f) very closely. The purpose of these provisions is to ensure that, except when the electronic protected health information disclosed to a plan sponsor is summary health information or enrollment or disenrollment information as provided for by § 164.504(f), group health plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained or transmitted to or by the plan sponsor on behalf of the group health plan. The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan; ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures; ensure that any agents, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate safeguards to protect the information; report to the group health plan any security incident of which it becomes aware; and make its policies and procedures and documentation relating to these safeguards available to the Secretary for purposes of determining the group

health plan's compliance with this subpart.

a. *Comment:* Several commenters expressed confusion concerning the applicability of proposed § 142.104 to security.

*Response:* The proposed preamble included language generally applicable to most of the proposed standards under HIPAA. Proposed § 142.104 concerned general requirements for health plans relative to processing transactions. We proposed that plans could not refuse to conduct a transaction as a standard transaction, or delay or otherwise adversely affect a transaction on the grounds that it was a standard transaction; health information transmitted and received in connection with a transaction must be in the form of standard data elements; and plans conducting transactions through an agent must ensure that the agent met all the requirements that applied to the health plan. Except for the statement that a plan's agent ("business associate" in the final rule) must meet the requirements (which would include security) that apply to the health plan, this proposed section did not pertain to the security standards and was addressed in the Transaction Rule.

b. *Comment:* The majority of comments concerned proposed rule language stating "the same level of security will be maintained at all links in the chain \* \* \*". Commenters believed the current language will have an adverse impact on one of the security standard's basic premises, which is scalability. It was requested that the language be changed to indicate that, while appropriate security must be maintained, all partners do not need to maintain the same level of security.

A number of commenters expressed some confusion concerning their responsibility for the security of information once it has passed from their control to their trading partner's control, and so on down the trading partner chain. Requests were made that we clarify that chain of trust partner agreements were really between two parties, and that, if a trading partner agreement has been entered into, any given partner would not be responsible, or liable, for the security of data once it is out of his or her control.

In line with this concern, several commenters were concerned that they would have some responsibility to ensure the level of security maintained by their trading partner.

Several commenters believe a chain of trust partner agreement should not be a security requirement. One commenter stated that because covered entities must already conform to the regulation

requirements, a “chain of trust” agreement does not add to overall security. Compliance with the regulation should be sufficient.

*Response:* We believe the commenters are correct that the rule as proposed would—(1) not allow for scalability; and (2) would lead an entity to believe it is responsible, and liable, for making sure all entities down the line maintain the same level of security. The confusion here seems to come from the phrase “same level of security.” Our intention was that each trading partner would maintain reasonable and appropriate safeguards to protect the information. We did not mean that partners would need to implement the same security technology or measures and procedures.

We have replaced the proposed “Chain of trust” standard with a standard for “Business associate contracts and other arrangements.”

When another entity is acting as a business associate of a covered entity, we require the covered entity to require the other entity to protect the electronic protected health information that it creates, receives, maintains or transmits on the covered entity’s behalf. The level of security afforded particular electronic protected health information should not decrease just because the covered entity has made the business decision to entrust a business associate with using or disclosing that information in connection with the performance of certain functions instead of doing those functions itself. Thus, the rule below requires covered entities to require their business associates to implement certain safeguards and take other measures to ensure that the information is safeguarded (see § 164.308(b)(1) and § 164.314(a)(1)).

The specific requirements of § 164.314(a)(1) are drawn from the analogous requirements at 45 CFR 164.504(e) of the Privacy Rule, although they have been adapted to reflect the objectives and context of the security standards. Compare, in particular, 45 CFR 164.504(e)(2)(ii) with § 164.314(a)(1). We have not imported all of the requirements of 45 CFR 164.504(e), however, as many have no clear analog in the security context (see, for example, 45 CFR 164.504(e)(2)(i) regarding permitted and required uses and disclosures made by a business associate). HHS had previously committed to reconciling its security and privacy policies regarding business associates (see 65 FR 82643). The close relationship of many of the organizational requirements in section 164.314 with the analogous requirements of the Privacy Rule should facilitate the implementation and

coordination of security and privacy policies and procedures by covered entities.

In contrast, when another entity is not acting as a business associate for the covered entity, but rather is acting in the capacity of some other sort of trading partner, we do not require the covered entity to require the other entity to adopt particular security measures, as previously proposed. This policy is likewise consistent with the general approach of the Privacy Rule (see the discussion in the Privacy Rule at 65 FR 82476). The covered entity is free to negotiate security arrangements with its non-business associate trading partners, but this rule does not require it to do so.

A similar approach underlies § 164.314(b) below. These provisions are likewise drawn from, and intended to support, the analogous privacy protections provided for by 45 CFR 164.504(f) (see the discussion of § 164.504(f) of the Privacy Rule at 65 FR 82507 through 82509, and 82646 through 82648). As with the business associate contract provisions, however, they are imported and adapted only to the extent they make sense in the security context. Thus, for example, the requirement at § 164.504(f)(2)(ii)(C) prohibits the plan documents from permitting disclosure of protected health information to the plan sponsor for employment-related purposes. As this prohibition goes entirely to the permissibility of a particular type of disclosure, it has no analog in § 164.314(b).

*c. Comment:* Several commenters stated that if security features are determined by agreements established between “trading partners,” as stated in the proposed regulations, there should be some guidelines or boundaries for those agreements so that extreme or unusual provisions are not permitted.

*Response:* This final rule sets a baseline, or minimum level, of security measures that must be taken by a covered entity and stipulates that a business associate must also implement reasonable and appropriate safeguards. This final rule does not, however, prohibit a covered entity from employing more stringent security measures or from requiring a business associate to employ more stringent security measures. A covered entity may determine that, in order to do business with it, a business associate must also employ equivalent measures. This would be a business decision and would not be governed by the provisions of this rule. Security mechanisms relative to the transmission of electronic protected health information between entities may need to be agreed upon by

both parties in order to successfully complete the transmission. However, the determination of the specific transmission mechanisms and the specific security features to be implemented remains a business decision.

*d. Comment:* Several commenters asked whether existing contracts could be used to meet the requirement for a trading partner agreement, or does the rule require entry into a new contract specific to this purpose. Also, the commenters want to know about those whose working agreements do not involve written contractual agreement: Do they now need to set up formal agreements and incur the additional expense that would entail?

*Response:* This final rule requires written agreements between covered entities and business associates. New contracts do not have to be entered into specifically for this purpose, if existing written contracts adequately address the applicable requirements (or can be amended to do so).

*e. Comment:* Several commenters asked whether covered entities are responsible for the security of all individual health information sent to them, or only information sent by chain of trust partners. They also asked if they can refuse to process standard transactions sent to them in an unsecured fashion. In addition, they inquired if they can refuse to send secured information in standard transactions to entities not required by law to secure the information. One commenter asked if there is a formula for understanding in any particular set of relationships where the ultimate responsibility for compliance with the standards would lie.

*Response:* Pursuant to the Transactions Rule, if a health plan receives an unsecured standard transaction, it may not refuse to process that transaction simply because it was sent in an unsecured manner. The health plan is not responsible under this rule, for how the transaction was sent to it (unless the transmission was made by a business associate, in which case different considerations apply); however, once electronic protected health information is in the possession of a covered entity, the covered entity is responsible for the security of the electronic protected health information received. The covered entity must implement technical security mechanisms to guard against unauthorized access to electronic protected health information that is transmitted over an electronic communication network. In addition, the rule requires the transmitting

covered entity to obtain written assurance from a business associate receiving the transmission that it will provide an adequate level of protection to the information. For the business associate provisions, see § 164.308(b) and § 164.314(a) of this final rule.

f. *Comment:* One commenter asked what security standards a vendor having access to a covered entity's health information during development, testing, and repair must meet and wanted to know whether the rule anticipates having a double layer of security compliance (one at the user level and one at the vendor level). If so, the commenter believes this will cause duplication of work.

*Response:* In the situation described, the vendor would be acting as a business associate. The covered entity must require the business associate to implement reasonable and appropriate security protections of electronic protected health information. This requirement, however, does not impose detailed requirements for how that level of protection must be achieved. The resulting flexibility should permit entities and their business associates to adapt their security safeguards in ways that make sense in their particular environments.

g. *Comment:* A number of commenters requested sample contract language or models of contracts. We also received one comment that suggested that we should not dictate the contents of contracted agreements.

*Response:* We will consider developing sample contract language as part of our guideline development.

#### *I. Policies and Procedures and Documentation Requirements (§ 164.316)*

We proposed requiring documented policies and procedures for the routine and nonroutine receipt, manipulation, storage, dissemination, transmission, and/or disposal of health information. We proposed that the documentation be reviewed and updated periodically.

We have emphasized throughout this final rule the scalability allowed by the security standards. This final rule requires covered entities to implement policies and procedures that are reasonably designed, taking into account the size and type of activities of the covered entity that relate to electronic protected health information, and requires that the policies and procedures must be documented in written form, which may be in electronic form. This final rule also provides that a covered entity may change its policies and procedures at any time, provided that it documents

and implements the changes in accordance with the applicable requirements. Covered entities must also document designations, for example, of affiliation between covered entities (see § 164.105(b)), and other actions, as required by other provisions of the subpart.

1. *Comment:* One commenter wanted development of written policies regarding such things as confidentiality and privacy rights for access to medical records, and approval of research by a review board when appropriate.

*Response:* These issues are covered in the Privacy Rule (65 FR 82462) (see, in particular, § 164.512(i), § 164.524, and § 164.530(i)).

2. *Comment:* One commenter asked if standards will override agreements that require others to maintain hardcopy documentation (for example, signature on file) and no longer require submitters to maintain hardcopy documentation.

*Response:* The security standards will require a minimum level of documentation of security practices. Any agreements between trading partners for the exchange of electronic protected health information that impose additional documentation requirements will not be overridden by this final rule.

3. *Comment:* One commenter stated that there should be a requirement to document only applications deemed necessary by an applications and data criticality assessment.

*Response:* Electronic protected health information must be afforded security protection under this rule regardless of what application it resides in. The measures taken to protect that information must be documented.

4. *Comment:* One commenter asked how detailed the documentation must be. Another commenter asked what "kept current" meant.

*Response:* Documentation must be detailed enough to communicate the security measures taken and to facilitate periodic evaluations pursuant to § 164.308(a)(8). While the term "current" is not in the final rule, this concept has been adopted in the requirement that documentation must be updated as needed to reflect security measures currently in effect.

5. *Comment:* We received one comment concerning review and updating of implementing documentation suggesting that "periodically" be changed to "at least annually."

*Response:* We believe that the requirement should remain as written, in order to allow individual entities to establish review and update cycles as deemed necessary. The need for review

and update will vary dependent upon a given entity's size, configuration, environment, operational changes, and the security measures implemented.

#### *J. Compliance Dates for Initial Implementation (§ 164.318)*

We proposed that how the security standard would be implemented by each covered entity would be dependent upon industry trading partner agreements for electronic transmissions. Covered entities would be able to adapt the security matrix to meet business needs. We suggested that requirements of the security standard may be implemented earlier than the compliance date. However, we would require implementation to be complete by the applicable compliance date, which is 24 months after adoption of the standard, and 36 months after adoption of the standard for small health plans, as provided by the Act. In the proposed rule, we suggested that an entity choosing to convert from paper to standard EDI transactions, before the effective date of the security standard, consider implementing the security standard at the same time.

In this final rule the dates by which entities must be in compliance with the standards are called "compliance dates," consistent with our practice in the Transactions, Privacy, and Employer Identifier Rules. Section 164.318 in this final rule is also organized consistent with the format of those rules. The substantive requirements, which are statutory, remain unchanged.

Many of the comments received concerning effective dates and compliance dates, including the compliance dates for modifications of standards, were addressed in the Transactions Rule. Those that were not addressed in that publication are presented below.

1. *Comment:* A number of commenters expressed support for the effective dates of the rules and stated that they should not be delayed. In contrast, one commenter stated that we should delay this rule to allow for an open consensus building debate to occur concerning security. One commenter asked that the rule be delayed until after implementation of the ICD-CM changes.

A number of comments were received expressing the opinion that the security regulation should not be published until either the Congress has enacted legislation governing standards with respect to the privacy of individually identifiable health information, or the Secretary of HHS has promulgated final regulations containing these standards. One commenter stated, "we find



ourselves in the difficult position of reacting to proposed rules setting the standards for how information should be physically and electronically protected, without having reached agreement on the larger issues of consent for and disclosure of individual medical information.”

*Response:* The effective date of the final rule is 60 days after this final rule is published in the **Federal Register**. The statute sets forth the compliance dates for the standards. Covered entities must comply with this final rule no later than 24 months (36 months for small plans) after the effective date.

The final Privacy Rule has already been published. We note that numerous comments concerning the timing of the adoption of privacy and security standards were also received in the privacy rulemaking and are discussed in the Privacy Rule at 65 FR 82752.

2. *Comment:* One commenter asked that proposed § 142.312 be rewritten to separate the effective dates for the Security Rule and the Transactions Rule.

*Response:* The proposed rule incorporated general language applicable to all the proposed Administrative Simplification standards. Language concerning standards other than Security is not included in § 164.318. Because this final rule is adopted after the Transactions Rule was adopted, the compliance dates for the security standards differ from those for the transactions standards. Comments concerning general effective dates were addressed in the Transactions Rule. Comments specific to the security standards are addressed here.

3. *Comment:* Several commenters suggested that we not allow early implementation of the Security Rules. A number of others asked that we allow, but not require, early implementation by willing trading partners. Another commenter suggested that early implementation by willing trading partners be allowed as long as the data content transmitted is equal to that required by statute. Another commenter requested that it be stipulated that entities cannot implement less than 1 year from the date of this final rule and then only after successful testing, and that a “start testing by” date be defined.

*Response:* Whether or not to implement before the compliance date is a business decision that each covered entity must make. Moreover, the vast majority of the standards address internal policies and procedures that can be implemented at any time without any impact on trading partners.

4. *Comment:* One commenter asked us to establish a research site or test laboratory for a trial implementation.

*Response:* The concept of a “trial implementation” that would have widespread relevance is inconsistent with our basic principles of flexibility, scalability, and technology-neutrality.

5. *Comment:* One commenter stated that the 2-year time frame for implementation of a contingency plan is too short for health plans that serve multiple regions of the country.

*Response:* The Congress mandated that entities must be in compliance 2 years from the initial standard’s adoption date (3 years for small plans).

#### K. Appendix

The proposed rule contained three addenda. Addendum 1 set out in matrix form the proposed requirements and related implementation features of the proposed rule. Addendum 2 set out in list form a glossary of terms with citations to the sources of those terms. Addendum 3 identified and mapped areas of overlap in the proposed security standard and implementation features.

This final rule retains only the first proposed addendum, the matrix, as an appendix, that is modified to reflect the changes in the administrative, physical, and technical safeguard portions of the rule below. Numerous terms in the glossary now appear in the rule below, typically (but not always) as definitions.

1. *Comment:* Over two-thirds of the comments received on this topic asked that the matrix be incorporated into the final rule. One commenter asked that a simplified version be made part of the final rule. Six commenters wanted it kept in this final rule as an addendum. One commenter stated that it should be in an appendix to the rule, while others stated that it should not be included in this final rule.

*Response:* Since a significant majority of commenters requested retention of the matrix, it has been incorporated into this final rule as an appendix. The matrix displays, in tabular form, the administrative, physical, and technical safeguard standards and relating implementation specifications described in this final rule in § 164.308, § 164.310, and § 164.312. It should be noted that the requirements of § 164.105, § 164.314, and § 164.316 are not presented in the matrix.

2. *Comment:* A large majority of commenters stated that the glossary located in Addendum 2 of the proposed rule should be included as part of the final rule. Several commenters asked that it be incorporated into the definitions section of the final rule. One

commenter stated that the glossary should not be part of this final rule.

*Response:* The terms defined in the glossary in Addendum 2 of the proposed rule are found throughout this final rule, either as part of the text of § 164.306 through § 164.312 or under § 164.304, as appropriate. We included only terms relevant to the particular standards and implementation specifications being adopted.

3. *Comment:* Several commenters requested that the mapped matrix located in Addendum 3 of the proposed rule be included in this final rule, either as part of the rule or as an addendum, while others stated that it should not be part of this final rule. Several commenters cited items to be added to the mapped matrix.

*Response:* The mapped matrix was merely a snapshot of current standards and guidelines that the implementation team was able to obtain for review during the development of the security and electronic signature requirements and was provided in the proposed rule as background material. Since this matrix has not been fully populated or kept up-to-date, it is not being published as part of this final rule. Where relevant, we do reference various standards and guidelines indicated in the matrix in this preamble.

#### L. Miscellaneous Issues

##### 1. Preemption

The statute requires generally that the security standards supersede contrary provisions of State law including State law requiring medical or health plan records to be maintained or transmitted in written rather than electronic formats. The statute provides certain exceptions to the general rule; section 1178(a)(2) of the Act identifies conditions under which an exception applies. The proposed rule did not provide for a process for making exception determinations; rather, a process was proposed in the privacy rulemaking and was adopted with the Privacy Rule (see part 160, subpart B). This process applies to exception determinations for all of the Administrative Simplification rules, including this rule.

a. *Comment:* Several commenters stated that the proposed rule does not include substantive protections for the privacy rights of patients’ electronic medical records, while the rule attempts to preempt State privacy laws with respect to these records. Comments stated that, by omitting a clarification of State privacy law applicability, the proposed rule creates confusion. They believe that the rule must contain



express and specific exemptions of State laws with respect to medical privacy.

*Response:* The Privacy Rule establishes standards for the rights of patients in regard to the privacy of their medical records and for the allowable uses and disclosures of protected health information. The identified concerns were discussed in the Privacy Rule (see 65 FR 82587 through 82588). The security standards do not specifically address privacy but will safeguard electronic protected health information against unauthorized access or modification.

b. *Comment:* One commenter asked how these regulations relate to confidentiality laws, which vary from State to State.

*Response:* It is difficult to respond to this question in the abstract without the benefit of reference to a specific State statute. However, in general, these security standards will preempt contrary State laws. Per section 1178(a)(2) of the Act, this general rule would not hold if the Secretary determines that a contrary provision of State law is necessary for certain identified purposes to prevent fraud and abuse; to ensure appropriate State regulation of insurance and health plans; for State reporting on health care delivery costs; or if it addresses controlled substances. See 45 CFR part 160 subpart B. In such case, the contrary provision of State law would preempt a Federal provision of these security standards. State laws that are related but not contrary to this final rule, will not be affected.

Section 1178 of the Act also limits the preemptive effect of the Federal requirements on certain State laws other than where the Secretary makes certain determinations. Section 1178(b) of the Act provides that State laws for reporting of disease and other conditions and for public health surveillance, investigation, or intervention are not invalidated or limited by the Administrative Simplification rules. Section 1178(c) of the Act provides that the Federal requirements do not limit States' abilities to require that health plans report or provide access to certain information.

c. *Comment:* Several commenters stated that allowing State law to establish additional security restrictions conflicts with the purpose of the Federal rule and/or would make implementation very difficult. One commenter asked for clarification as to whether additional requirements tighter than the requirements outlined in the proposed rule may be imposed.

*Response:* The general rule is that the security standards in this final rule supersede contrary State law. Only where the Secretary has granted an exception under section 1178(a)(2)(A) of the Act, or in situations under section 1178(b) or (c) of the Act, will the general rule not hold true. Covered entities may be required to adhere to stricter State-imposed security measures that are not contrary to this final rule.

## 2. Enforcement

The proposed rule did not contain specific enforcement provisions. This final rule likewise does not contain specific enforcement provisions; it is expected that enforcement provisions applicable to all Administrative Simplification rules will be proposed in a future rulemaking.

a. *Comment:* One commenter voiced support for the proposed rule's approach. Another stated that the process is poorly defined. One commenter stated that fines should be eliminated, or the scope of activity subject to fines should be more narrowly defined.

While a number of commenters were of the opinion that HHS must retain enforcement responsibility, stating that it would be unconstitutional to give it to a private entity, several others stated that it may not be practical for HHS to retain the responsibility for determining violations and imposing penalties specified by the statute. A concern was voiced over HHS's ability to fairly and consistently apply the rules due to budget constraints. Several commenters support industry solutions to enforcement with some level of government involvement. One commenter recommended a single audit process using accrediting bodies already in place. Another stated that entities providing accreditation services should not be involved in enforcement as this would result in a conflict of interest.

Clarification was requested, including the use of examples, concerning what constitutes a violation, and how a penalty applies to a "person." Commenters asked if the term "person" referred to the people responsible for the system and how penalties would apply to corporations and other entities.

*Response:* It is expected that enforcement of HIPAA standards will be addressed in regulations to be issued at a later date.

b. *Comment:* Several commenters stated that enforcement of the security standards will be arbitrarily delegated to private businesses that compete with physicians and with each other.

*Response:* These comments are premature for the reasons stated above.

## 3. Comment Period

The comment period on the proposed rule was 60 days.

*Comment:* We received comments suggesting that significant changes to the standards could occur in the final rule as a result of changes made in response to comments. The commenter believes such changes could adversely affect payers and providers, and suggested that the rule should be republished as a proposed rule with a new comment period to allow additional comments concerning any changes. A "work-in-progress" approach was also suggested, to give all stakeholders time to read, analyze, and comment upon evolving versions of a particular proposed rule.

*Response:* We have not accepted these suggestions. The numerous comments received were thoughtful, analytical, detailed, and addressed every area of the proposed rule. This response to the proposed rule indicates that the public had ample time to read, analyze, and comment upon the proposed rule. If we were to treat the rule as a "work-in-progress" and issue evolving versions, allowing for comments to each version, we would never implement the statute and achieve administrative simplification as directed by the Congress.

## M. Proposed Impact Analysis

The preamble to the Transactions Rule contains comments and responses on the impact of all the administrative simplification standards in general except privacy. Comments and responses specific to the relative impact of implementing this final rule are presented below.

a. *Comment:* Several commenters stated that the proposed security standards are complex, costly, administratively burdensome, and could result in decreased use of EDI. One commenter stated that this rule runs counter to the explicit intent of Administrative Simplification that requires, "any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care."

Several commenters expressed concern that there was no cost benefit analysis provided for these proposed regulations, stating that, faced with increasingly limited resources, it is essential that a security standards cost/benefit analysis for all health care trading partners be provided. Another said an independent cost estimate by the General Accounting Office (GAO) should be performed on these rules and

HHS cost estimates should be publicized for comparison purposes.

Still another commenter stated that HHS must provide accurate public sector implementation cost figures and provide funds to offset the cost burden.

One commenter asked for cost benefit evaluations to understand the relationship between competing technologies, levels of security and potential threats to be guarded against. These would demonstrate the costs and the benefits to be gained for both large and small organizations and would provide an understanding of how the levels of security vary by organization size and what the inducements and support available to facilitate adoption are. One commenter suggested that we establish a workgroup to more fully assess the costs and provide Federal funds to offset implementation costs.

One commenter noted a seeming disconnect between two statements in the preamble. Section A, Security standards, states, "no individual small entity is expected to experience direct costs that exceed benefits as a result of this rule." In contrast, section E, Factors in establishing the security standards reads, "We cannot estimate the per-entirety cost of implementation because there is no information available regarding the extent to which providers', plans', and clearinghouses' current security practices are deficient."

*Response:* We are unable to estimate, of the nation's 2 million-plus health plans and 1 million-plus providers that conduct electronic transactions, the number of entities that would require new or modified security safeguards and procedures beyond what they currently have in place. Nor are we able to estimate the number of entities that neither conduct electronic transactions nor maintain individually identifiable electronic health information but may become covered entities at some future time. As we are unable to estimate the number of entities and what measures are or are not already in place, or what specific implementation will be chosen to meet the requirements of the regulation, we are also unable to estimate the cost to those entities.

However, the use of electronic technology to maintain or transmit health information results in many new and potentially large risks. These risks represent expected costs, both monetary and social. Leaving risk assessment up to individual entities will minimize the impact and ensure that security effort is proportional to security risk.

As discussed earlier, the security requirements are both scalable and technically flexible. We have made significant changes to this final rule,

reducing the number of required implementation features and providing for greater flexibility in satisfaction of the requirements. In other words, we have focused more on what needs to be done and less on how it should be accomplished.

We have removed the statement regarding the extent of costs versus benefits for small entities.

b. *Comment:* One commenter stated that on page 43262 of the proposed rule, it indicate that complexity of conversion to the security standards would be affected by the choice to use a clearinghouse. The commenter stated that this choice would have little effect on implementation of security standards. Another commenter stated that the complexity (and cost) of the conversion to meet the security standards is affected by far more than just the "volume of claims health plans process electronically and the desire to transmit the claims or to use the services of a VAN or clearinghouse" as is stated on page 43262. Because the security standards apply to internal systems as well as to transactions between entities, a number of additional factors must be considered, for example, modification of existing security mechanisms, legacy systems, architecture, and culture.

*Response:* We agree. We have modified the Regulatory Impact Analysis section to take into account that there are other factors involved, such as the architecture and technology limitations of existing systems.

c. *Comment:* One commenter stated that States will need 90 percent funding of development and implementation, without the burden of an advanced planning documents requirement, from us for this costly process to succeed. Any new operational obligation should be 100 percent funded. Also human resource obligations will be significant. Some States believe they will have difficulty obtaining the budget funds for the State share of the costs. State Medicaid agencies, as purchasers, may also face paying the implementation costs of health care providers, clearinghouses, and health plans in the form of higher rates.

*Response:* The statute does not authorize any new or special funding for implementation of the regulations. Medicaid system changes, simply because they are "HIPAA related" do not automatically qualify for 90 percent Federal funding participation. As with any systems request, the usual rules will be applied to determine funding eligibility for State HIPAA initiatives. Nevertheless, HHS recognizes that there are significant issues regarding the

funding and implementation of HIPAA by Medicaid State agencies, and intends to address them through normal channels of communication with States.

d. *Comment:* One commenter stated that the proposed rule does not establish how the security standards will contribute to reduced cost for providers. One commenter expected the unintended result of this regulation will be impediment of EDI growth and perhaps even a decline in EDI use by providers. Another stated that the proposed rule actively discourages physician EDI participation by suggesting a fallback to paper processing for those unable to meet the cost of highly complex security compliance.

*Response:* Ensuring the integrity of an electronic message, its delivery to the correct person, and its confidentiality must be an integral part of conducting electronic commerce. We believe that the consistent application of the measures provided in this rule will actually encourage use of EDI because it will provide increased confidence in the reliability and confidentiality of health information to all parties involved.

Also, the implementation of these security requirements will reduce the potential overall cost of risk to a greater extent than additional security controls will increase costs. Put another way, the potential cost of not reasonably addressing security risks could substantially exceed the cost of compliance.

e. *Comment:* One commenter stated that the implementation impact of the technical safeguards is clearly understated for physicians who use digitally-based equipment that has been in place for some time. The commenter believes that the rule will likely have greatest impact on the installed base of digital systems, including imaging modalities and other medical devices that store or transmit patient information because software for legacy systems will likely require retrofitting or replacement to come into compliance. The commenter believes that this is a negative impact and would outweigh any benefits derived from the potential risk of security breaches. The commenter recommended compliance for digital imaging devices be extended by an additional 3 years to allow time to upgrade systems and defray the associated costs.

*Response:* Compliance dates for the initial implementation of the initial standards are statutorily prescribed; therefore, we are unable to allow additional time outside of the statutory timeframes for compliance.

f. *Comment:* A commenter stated that, as a new regulatory mandate, HIPAA

costs must be factored into any base year calculations for the proposed prospective payment system. Without an adjustment, this will be another regulatory mandate that comes at the cost of patient care.

*Response:* Costs included in the prospective payment system are legislatively mandated. The Congress did not direct the inclusion of HIPAA costs into the system, so they are not included. However, the Department believes that the HIPAA standards will provide savings to the provider community over the next 10 years.

*g. Comment:* One commenter suggested that we include requirements for how a compliant business could dually operate—(1) in a HIPAA compliant manner; and (2) in their former noncompliant manner in order to accommodate doing business with other organizations that are not yet compliant.

*Response:* The statute imposes a 2-year implementation period between the adoption of the initial standards and the date by which covered entities (except small health plans) must be in compliance. An entity may come into compliance at any point in time during the 2 years. Therefore, the rule does not require a covered entity to comply before the established compliance date. Those entities that come into compliance before the 2-year deadline should decide how best to deal with entities that are not yet compliant. Further, we note that, generally speaking, compliance by a covered entity with these security rules will not hinge on compliance by other entities.

*h. Comment:* One commenter stated that privacy legislation could impose significant changes to written policies and procedures on authorization, access to health information, and how sensitive information is disclosed to others. The commenter believes these changes could mean the imposition of security requirements different from those contained in the proposed rule, and money spent complying with the security provisions could be ill spent if significant new requirements result from the privacy legislation.

*Response:* The privacy standards at subpart E of 42 CFR part 164 are now in effect, and this final rule is compatible with them. If, in the future, the Congress passes a law whose provisions differ from these standards, the standards would have to be modified.

*i. Comment:* One commenter stated that the private sector should develop educational tools or models in order to assist physicians, other providers, and health plans to comply with the security regulations.

*Response:* We agree. The health care industry is striving to do this. HHS is also considering provider outreach and education activities.

#### IV. Provisions of the Final Regulation

We have made the following changes to the provisions of the August 12, 1998 proposed rule. Specifically, we have—

- Changed the CFR part from 142 to 164.
- Removed information throughout the document pertaining to electronic signature standards. Electronic signature standards will be published in a separate final rule.
- Replaced the word “requirement,” when referring to a standard, with “standard.” Replaced “Implementation feature” with “Implementation specification.”
- Made minor modifications to the text throughout the document for purposes of clarity.
- Modified numerous implementation features so that they are now addressable rather than mandatory.
- Removed the word “formal” when referring to documentation.
- Revised the phrase “health information pertaining to an individual” to “electronic protected health information.”
- Added the following definitions to § 160.103: “Disclosure,” “Electronic protected health information,” “Electronic media,” “Organized health care arrangement,” and “Use.”
- Removed proposed § 142.101 as this information is conveyed in § 160.101 and § 160.102 of the Privacy Rule (65 FR 82798). Removed proposed § 142.102 as it is redundant.
- Removed the following definitions from proposed § 142.103 since they are pertinent to other administrative simplification regulations and are defined elsewhere: code set, health care clearinghouse, health care provider, health information, health plan, medical care, small health plan, standard, and transaction.
- Moved the following definitions from § 164.501 to § 164.103 (proposed § 142.103): “Plan sponsor” and “Protected health information.” Added definitions of “Covered functions” and “Required by law.”
- Removed proposed § 142.104, “General requirements for health plans,” and proposed § 142.105, “Compliance using a health care clearinghouse,” since these sections are not pertinent to the security standards.
- Removed proposed § 142.106, “Effective dates of a modification to a standard or implementation specification,” since this information is

covered in the “Standards for Electronic Transactions” final rule (65 FR 50312).

- Moved proposed § 142.302 to § 164.302. Changed the section heading from “Applicability and scope” to “Applicability.” Modified language to state that covered entities must comply with the security standards.

- Moved proposed § 142.304 to § 164.304. Modified language to remove definitions of words and concepts not used in this final rule: “Access control,” “Contingency plan,” “Participant,” “Role-based access control,” “Token,” and “User-based access.”

- Moved proposed § 142.304 to § 164.304. Modified language to add definitions requested by commenters; previously published in Addendum 2 but not in the draft regulation itself; or necessitated by the change of scope to electronic protected health information and alignment with the Privacy Rule to include: “Administrative safeguards,” “Availability,” “Confidentiality,” “Data,” “Data authentication Code,” “Integrity,” “Electronic protected health information,” “Facility,” “Information System,” “Security or security measures,” “Security incident,” “Technical safeguards,” “User,” and “Workstation.”

- Moved definitions related to privacy from § 164.504 to new § 164.103: “Common control,” “Common ownership,” “Health care component,” “Hybrid entity.”

- Moved proposed § 142.306, “Rules for the security Standard,” to § 164.306. Modified language to more clearly state the general requirements of the final rule relative to the standards and implementation specifications contained therein. Retitled the section as “Security standards: General Rules.”

- Moved proposed § 142.308 to § 164.308. Where this section was proposed to contain all of the security standards in paragraphs (a) through (d), it now encompasses the Administrative safeguards.

- Moved and reorganized proposed § 142.308 (a) through (d) requirements to § 164.308, § 164.310, and § 164.312.

- Moved proposed § 142.308(a)(1), “Certification,” to § 164.308(a)(8). Modified language to indicate both technical and nontechnical evaluation is involved and renamed “Evaluation.”

- Moved proposed § 142.308(a)(2), “Chain of trust,” to § 164.308(b)(1), renamed to “Business associate contracts and other arrangements,” and revised language to redefine who must enter into a contract under this rule for the protection of electronic protected health information.

- Moved proposed § 142.308(a)(3), “Contingency plan,” to

§ 164.308(a)(7)(i). Modified language to state that two implementation specifications, “Applications and data criticality analysis” and “Testing and revision procedures,” are addressable.

- Removed “Formal mechanism for processing records” (proposed § 142.308(a)(4)) since this requirement was determined to be in part intrusive into business functions and in part redundant.

- Moved proposed § 142.308(a)(5), “Information access control,” to § 164.308(a)(4)(i) and renamed as “Information access management.” Removed the word “formal” from description. Modified language to state that two implementation specifications (“Access Authorization” and Access Establishment and Modification”) are addressable.

- Moved proposed § 142.308(a)(6), “Internal audit,” to § 164.308(a)(1)(ii)(D) as an implementation specification under the “Security management process” standard since this was determined to be a more logical placement of this item. Retitled, for clarity, “Information system activity review.”

- Moved proposed § 142.308(a)(7), “Personnel security,” to § 164.308(a)(3)(i) and retitled “Workforce security.” Modified language to state that implementation specifications are addressable.

- Combined proposed § 142.308(a)(7)(i), and § 142.308(a)(7)(iii) (“Assuring supervision of maintenance personnel by an authorized, knowledgeable person” and “Assuring that operations and maintenance personnel have proper access authorization,”) under § 164.308(a)(3)(ii)(A) and renamed to “Authorization and/or supervision.” Modified description for clarity.

- Moved proposed § 142.308(a)(7)(iv), “Personnel clearance procedure,” to § 164.308(a)(3)(ii)(B), renamed to “Workforce clearance procedure,” and modified description for clarity.

- Removed proposed § 142.308(a)(7)(v), “Personnel security policies and procedures,” as this feature was determined to require redundant effort.

- Removed proposed § 142.308(a)(7)(vi), “Security awareness training.” Information concerning this subject has been incorporated under § 164.308(a)(5)(i), “Security awareness and training.”

- Removed proposed § 142.308(a)(8), “Security configuration management,” and all implementation features, except “Documentation” (hardware and/or software installation, Inventory, Security testing, and Virus checking),

since this requirement was determined to be redundant. “Documentation” has been made a discrete standard at § 164.316.

- Moved proposed § 142.308(a)(9), “Security incident procedures,” to § 164.308(a)(6)(i) and reworded for clarity. Combined “Report procedures” and “Response procedures” features into a single required implementation specification, named “Response and Reporting” at § 164.308(a)(6)(ii).

- Moved proposed § 142.308(a)(10), “Security management process,” to § 164.308(a)(1).

- Moved proposed § 142.308(a)(10)(i), “Risk analysis,” to § 164.308(a)(1)(ii)(A).

- Moved proposed § 142.308(a)(10)(ii), “Risk management,” to § 164.308(a)(1)(ii)(B).

- Moved proposed § 142.308(a)(10)(iii), “Sanction policy,” to § 164.308(a)(1)(ii)(C).

- Removed proposed § 142.308(a)(10)(iv), “Security policy,” since this requirement was determined to be redundant.

- Moved proposed § 142.308(a)(11), “Termination,” to § 164.308(a)(3)(ii)(C) as an addressable implementation specification under the “Workforce security” standard, and renamed as “Termination procedures”. Removed “Termination” implementation features (changing locks, removal from access lists, removal of user accounts, turning in of keys, tokens, or cards) since these were determined to be too specific.

- Moved proposed § 142.308(a)(12), “Training,” to § 164.308(a)(5)(i) and renamed as “Security awareness and training.” Language modified to incorporate all training information under this one standard. Revised and made addressable all implementation specifications under this standard.

- Moved proposed § 142.308(b), “Physical safeguards to guard data integrity, confidentiality and availability,” to § 164.310 and renamed as “Physical safeguards.” Removed specific reference to locks and keys.

- Moved proposed § 142.308(b)(1), “Assigned security responsibility requirement,” to § 164.308(a)(2) since this has been determined to be an administrative procedure. Modified language to clarify that responsibility could be assigned to more than one individual.

- Moved proposed § 142.308(b)(2), “Media controls,” to § 164.310(d)(1) and renamed as “Device and media controls.” Removed the word “formal.” Added “Media re-use” as a required implementation specification at § 164.310(d)(2)(ii).

- Removed proposed § 142.308(b)(2)(i), “Access control,”

implementation feature as it was determined to be redundant.

- Moved proposed § 142.308(b)(2)(ii), “Accountability” implementation feature to § 164.310(d)(2)(iii), and made it an addressable implementation specification.

- Combined proposed § 142.308(b)(2)(iii), “Data backup,” implementation feature with proposed § 142.308(b)(2)(iv), “Data storage” implementation feature, renamed as “Data backup and storage”, moved to § 164.310(d)(2)(iv), and made it an addressable implementation specification.

- Moved proposed § 142.308(b)(2)(v), “Data disposal,” implementation feature to § 164.310(d)(2)(i) and made it a required implementation specification.

- Moved proposed § 142.308(b)(3), “Physical access controls,” to § 164.310(a)(1) and renamed as “Facility access controls.” Removed word “formal.”

- Moved proposed § 142.308(b)(3)(i), “Disaster recovery,” implementation feature to § 164.310(a)(2)(i). It is now part of the “Contingency operations” implementation specification.

- Moved proposed § 142.308(b)(3)(ii), “Emergency mode operations,” implementation feature to § 164.310(a)(2)(i). It is now part of the “Contingency operations” implementation specification.

- Removed proposed § 142.308(b)(3)(iii), “Equipment control (into and out of site),” as this information is now covered under § 164.310(d)(1), “Device and media controls.”

- Moved proposed § 142.308(b)(3)(iv), “A facility security plan,” to § 164.310(a)(2)(ii).

- Moved proposed § 142.308(b)(3)(v), “Procedure for verifying access authorizations,” to § 164.310(a)(2)(iii) and renamed as “Access control and validation procedures.” Removed the word “formal” from text.

- Moved proposed § 142.308(b)(3)(vi), “Maintenance records,” to § 164.310(a)(2)(iv).

- Moved proposed § 142.308(b)(3)(vii), “Need to know procedures for personnel access,” to § 164.310(a)(2)(iii) and renamed as “Access control and validation procedures.”

- Moved proposed § 142.308(b)(3)(viii), “Procedures to sign in visitors and provide escort, if appropriate,” to § 164.310(a)(2)(iii) and renamed as “Access control and validation procedures.”

- Moved proposed § 142.308(b)(3)(ix), “Testing and revision,” to § 164.310(a)(2)(iii) and renamed as “Access control and validation procedures.”

- Moved proposed § 142.308(b)(4), “Policy and guidelines on workstation use,” to § 164.310(b) and renamed as “Workstation use.”

- Moved proposed § 142.308(b)(5), “Secure work station location,” to § 164.310(c) and renamed as “Workstation security.”

- Removed proposed § 142.308(b)(6), “Security awareness training,” as a separate requirement. This requirement has been incorporated under § 164.308(a)(5)(i), “Security awareness and training.”

- Combined and moved proposed § 142.308(c) and § 142.308(d), “Technical security services to guard data integrity, confidentiality and availability” and “Technical security mechanisms,” to § 164.312 and renamed as “Technical safeguards.”

- Removed proposed § 142.308(c)(1) since it is no longer pertinent.

- Moved proposed § 142.308(c)(1)(i), “Access control,” to § 164.312(a)(1).

- Moved proposed § 142.308(c)(1)(i)(A), “Procedure for emergency access,” to § 164.312(a)(2)(ii), and renamed as “Emergency access procedures.”

- Removed proposed § 142.308(c)(1)(i)(B).

- Removed proposed § 142.308(c)(1)(i)(B)(1), “Context-based access,” § 142.308(c)(1)(i)(B)(2), “Role-based access,” and

- § 142.308(c)(1)(i)(B)(3), “User-based access,” since these features were deemed too specific and were perceived as the only options permissible.

- Moved proposed § 142.308(c)(1)(i)(C), “Optional use of encryption,” to § 164.312(a)(2)(iv) and retitled “Encryption and decryption.”

- Moved proposed § 142.308(c)(1)(ii), “Audit controls,” to § 164.312(b).

- Removed proposed § 142.308(c)(1)(iii), “Authorization control,” and all implementation features (Role-based access, User-based access) since this function has been incorporated into § 164.308(a)(4), “Information access management.”

- Moved proposed § 142.308(c)(1)(iv), “Data authentication,” to § 164.312(c)(1), and retitled as “Integrity.” Reworded part of description and placed in § 164.312(c)(2), “Mechanism to authenticate data,” a new, addressable implementation specification. Removed reference to double keying.

- Moved proposed § 142.308(c)(1)(v), “Entity authentication,” to § 164.312(d)

and retitled as “Person or entity authentication.”

- Moved proposed § 142.308(c)(1)(v)(A), “Automatic logoff,” to § 164.312(a)(2)(iii).

- Moved proposed § 142.308(c)(1)(v)(B), “Unique user identification,” to § 164.312(a)(2)(i).

- Removed proposed § 142.308(c)(1)(v)(C) since text is no longer pertinent.

- Removed proposed § 142.308(c)(1)(v)(C)(2), “Password,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(3), “PIN,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(4), “Telephone callback,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(5), “Token,” as too specific.

- Removed proposed § 142.308(c)(2), as no longer relevant.

- Moved proposed § 142.308(d)(1), “Communications or network controls,” to § 164.312(e)(1) and renamed as “Transmission security.”

- Removed proposed § 142.308(d)(1)(i), since it is no longer pertinent.

- Moved proposed § 142.308(d)(1)(i)(A), “Integrity controls,” to § 164.312(e)(2)(i) and reworded for clarity.

- Removed proposed § 142.308(d)(1)(i)(B), “Message authentication,” since this subject is now covered under § 164.312(e)(2)(i), “Integrity controls.”

- Removed proposed § 142.308(d)(1)(ii) text since it is no longer pertinent.

- Removed proposed § 142.308(d)(1)(ii)(A), “Access controls.”

- Moved proposed § 142.308(d)(1)(ii)(B), “Encryption,” to § 164.312(e)(2)(ii) and reworded to enhance flexibility and scalability.

- Removed proposed § 142.308(d)(2) text regarding: “Network controls,” and all implementation features (“Alarm,” “Audio trail,” “Entity authentication,” “Event reporting”).

- Removed proposed § 142.310, “Electronic signature,” and all subheadings. This section will be issued as a separate future regulation.

- Moved proposed § 142.310 “Electronic signature Standard,” to § 164.310. Where this section was proposed to contain the electronic signature standard, it now encompasses the “Physical safeguards.”

- Moved proposed § 142.312, “Effective date of the implementation of the security and electronic signature

standards,” to § 164.318 and retitled as “Compliance dates for the initial implementation of the security standards.” Reworded and retitled subsections.

- Added § 164.105, “Organizational requirements,” with two standards, “Health care component and “Affiliated covered entities” with related implementation specifications.

- Added § 164.310(d)(2)(ii), “Media re-use procedures,” implementation specification.

- Added § 164.312, “Technical safeguards,” encompassing the combined technical services and technical mechanisms standards (proposed § 142.308(c) and (d)).

- Added § 164.314, “Organizational requirements.”

- Added § 164.314(a)(1), “Business associate contracts or other arrangements” standard and related implementation specifications.

- Added § 164.314(b)(1), “Requirements for group health plans” standard and related implementation specifications.

- Added § 164.316, “Policies and procedures and documentation requirements.”

- Added § 164.316(a), “Policies and procedures” standard.

- Added § 164.316(b)(1), “Documentation” standard and related implementation specifications.

- Added § 164.318, “Compliance dates for the initial implementation of the security standards.”

- Renamed Addendum 1 as Appendix A.

- Removed Addendum 2. Definitions of terms used in this final rule are now incorporated into § 164.103 and § 164.304, or within the rule itself.

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As discussed below, we are soliciting comment on the recordkeeping requirements, as referenced in § 164.306, § 164.308, § 164.310, § 164.314, and § 164.316 of this document.

#### *Section 164.306 Security Standards: General Rules*

Under paragraph (d), a covered entity must, if implementing the implementation specification is not reasonable and appropriate, document why it would not be reasonable and appropriate to implement the implementation specification.

We estimate that 75,000 entities will be affected by this requirement and that they will have to create documentation 3 times for this requirement. We estimate each instance of documentation will take .25 hours, for a one-time total burden of 56,250 hours.

#### *Section 164.308 Administrative Safeguards*

Under this section, a covered entity must document known security incidents and their outcomes.

We estimate that there will be 50 known incidents annually and that it will take 8 hours to document this requirement, for an annual burden of 400 hours.

This section further requires that each entity have a contingency plan, with specified components.

We estimate that there will be 60,000 entities affected by this requirement and that it will take each entity 8 hours to comply, for a total one-time burden of 480,000 hours.

This section also requires that the written contract or other arrangement with a business associate document the satisfactory assurances that the business associate will appropriately safeguard the information through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to document their arrangements via written contracts and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

#### *Section 164.310 Physical Safeguards*

This section requires that a covered entity implement policies and procedures to document repairs and modifications to the physical components of a facility that are related to security (for example, hardware, walls, doors, and locks).

We believe that 15,500 entities will have to repair or modify physical components, most of which will need to be done in the first year of implementation. In the following years, we estimate that 500 entities will need to make repairs or modifications. We estimate that it will take 10 minutes to document each repair or modification for a burden of 2,583 hours the first year and 83 hours annually subsequently.

This section requires that a covered entity create a retrievable, exact copy of electronic protected health information, where needed, before movement of equipment.

We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to backup their data files, and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

#### *Section 164.314 Organizational Requirements*

This section requires that a covered entity report to the Secretary problems with a business associate's pattern of an activity or practice of the business associate that constitute a material breach or violation of the business associate's obligation under the contract or other arrangement if it is not feasible to terminate the contract or arrangement.

We believe that 10 entities will need to comply with this reporting requirement and that it will take them 60 minutes to comply with this requirement for an annual burden of 10 hours.

This section also requires that a covered entity may, if a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in § 160.103 of this subchapter to a covered entity, permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of paragraph (a)(2)(i) of this section, provided that the covered

entity attempts in good faith to obtain satisfactory assurances as required by paragraph (a)(2)(ii)(A) of this section, and documents the attempt and the reasons that these assurances cannot be obtained.

We believe that this situation will affect 20 entities and that it will take 60 minutes to document attempts to obtain assurances and the reasons they cannot be obtained for an annual burden of 20 hours.

This section further requires that business associate contracts or other arrangements and group health plans must require the business entity and plan sponsor, respectively, to report to the covered entity any security incident of which it becomes aware.

We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to document their agreements via written contracts, and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

#### *Section 164.316 Policies and Procedures and Documentation Requirements*

Paragraph (b)(1), *Standard: Documentation*, of this section requires a covered entity to—

(i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity, assessment, or designation is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, assessment, or designation.

We estimate that it will take the 4,000,000 entities covered by this final rule 16 hours to document their policies and procedures, for a total one-time burden of 64,000,000 hours.

The total annual burden of the information collection requirements contained in this final rule is 64,539,264 hours. These information collection requirements will be submitted to OMB for review under the PRA and will not become effective until approved by OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Reports

Clearance Officer, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Julie Brown, CMS–0049–F; and  
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

#### IV. Regulatory Impact Analysis

##### A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Although we cannot determine the specific economic impact of the standards in this final rule (and individually each standard may not have a significant impact), the overall impact analysis makes clear that, collectively, all the standards will have a significant impact of over \$100 million on the economy. Because this rule affects over 2 million entities, a requirement as low as \$50 per entity would render this rule economically significant. This rule requires each of these entities to engage in, for example, at least some risk assessment activity; thus, this rule is almost certainly economically significant even though we do not have an estimate of the marginal impact of the additional security standards. However, the standards adopted in this rule are considerably more flexible than those anticipated in the overall impact analysis. Therefore, their implementation costs should be lower than those assumed in the impact analysis.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses,

nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. While each standard may not have a significant impact on a substantial number of small entities, the combined effects of all the standards are likely to have a significant effect on a substantial number of small entities. Although we have certified this rule as having a significant impact, we have previously discussed the impact of small entities in the RFA published as part of the August 17, 2000 final regulation for the Standards for Electronic Transactions (65 FR 50312), on pages 50359 through 50360. That analysis included the impact of the set of HIPAA standards regulations (transactions and code sets, identifiers, and security). Although we discussed the impact on small entities in the previous analysis, we would like to discuss how this final rule has been structured to minimize the impact on small entities, compared to the proposed rule.

The proposed rule mandated 69 implementation features for all entities. A large number of commenters indicated that mandating such a large number would be burdensome for all entities. As a result, we have restructured this final rule to permit greater flexibility. While all standards must be met, we are now only requiring 13 implementation specifications. The remainder of the implementation specifications is “addressable.” For addressable specifications, an entity decides whether each specification is a reasonable and appropriate security measure to apply within its particular security framework. This decision is based on a variety of factors, for example, the entity’s risk analysis, what measures are already in place, the particular interest to small entities, and the cost of implementation.

Based on the decision, an entity can—(1) implement the specification if reasonable and appropriate; (2) implement an alternative security measure to accomplish the purposes of the standard; or (3) not implement anything if the specification is not reasonable and appropriate and the standard can still be met.

This approach will provide flexibility for all entities, and especially small entities that would be most concerned about the cost and complexity of the security standards. Small entities can look at the addressable implementation specifications and tailor their compliance based on their risks and capabilities of addressing those risks.

The required risk analysis is also a tool to allow flexibility for entities in meeting the requirements of this final rule. The risk analysis requirement is designed to allow entities to look at their own operations and determine the security risks involved. The degree of response is determined by the risks identified. We assume that smaller entities, who deal with smaller amounts of information would have smaller physical facilities, smaller work forces, and therefore, would assume less risk. The smaller amount of risk involved means that the response to that risk can be developed on a smaller scale than that for larger organizations.

Individuals and States are not included in the definition of a small entity. However, the security standards will affect small entities, such as providers and health plans, and vendors in much the same way as they affect any larger entities. Small providers who conduct electronic transactions and small health plans must meet the provisions of this regulation and implement the security standards. A more detailed analysis of the impact on small entities is part of the impact analysis published on August 17, 2000 (65 FR 50312), which provided the impact for all of the HIPAA standards, except privacy. As we discussed above, the scalability factor of the standards means that the requirements placed upon small providers and plans would be consistent with the complexity of their operations. Therefore, small providers and plans with appropriate security processes in place would need to do relatively little in order to comply with the standards. Moreover, small plans will have an additional year to come into compliance.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. While this rule may have a significant impact on small rural hospitals, the impact should be minimized by the scalability factors of the standards, as discussed above in the impact on all small entities. In addition, we have previously discussed the impact of small entities in the RIA published as part of the August 17, 2000 final regulation for the Standards for Electronic Transactions.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995



also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We estimate that implementation of all the standards will require the expenditure of more than \$110 million by the private sector. Therefore, the rule establishes a Federal private sector mandate and is a significant regulatory action within the meaning of section 202 of UMRA (2 U.S.C. 1532). We have included the statements to address the anticipated effects of these rules under section 202.

These standards also apply to State and local governments in their roles as health plans or health care providers. Because these entities, in their roles as health plans or providers, must implement the requirements in these rules, the rules impose unfunded mandates on them. Further discussion of this issue can be found in the previously published impact analysis for all standards (65 FR 50360 through 50361).

The anticipated benefits and costs of the security standards, and other issues raised in section 202 of the UMRA, are addressed in the analysis below, and in the combined impact analysis. In addition, as required under section 205 of the UMRA (2 U.S.C. 1535), having considered a reasonable number of alternatives as outlined in the preamble to this rule, HHS has concluded that this final rule is the most cost-effective alternative for implementation of HHS's statutory objective of administrative simplification.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule was published before the enactment of Executive Order 13132 of August 4, 1999, Federalism (published in the **Federal Register** on August 10, 1999 (64 FR 43255)), which required meaningful and timely input by State and local officials in the development of rules that have Federalism implications). However, we received and considered comments on the proposed rule from State agencies and from entities who conduct transactions with State agencies. Several of the comments referred to the costs that will result from implementation of the HIPAA standards. As we stated in the impact analysis, we are unable to estimate the cost of implementing

security features as implementation needs will vary dependent upon a risk assessment and upon what is already in place. However, the previously referenced impact analysis in the August 17, 2000 final rule (65 FR 50312) showed that Administrative Simplification costs will be offset by future savings.

In complying with the requirements of part C of title XI, the Secretary established interdepartmental implementation teams who consulted with appropriate State and Federal agencies and private organizations. These external groups consisted of the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security, the Workgroup for Electronic Data Interchange (WEDI), the National Uniform Claim Committee (NUCC), the National Uniform Billing Committee (NUBC), and the American Dental Association (ADA). The teams also received comments on the proposed regulation from a variety of organizations, including State Medicaid agencies and other Federal agencies.

#### *B. Anticipated Effects*

The analysis in the August 2000, Transaction Rule included the expected costs and benefits of the administrative simplification regulations related to electronic systems for 10 years. Although only the electronic transaction standards were promulgated in the transaction rule, HHS expected affected parties to make systems compliance investments collectively because the regulations are so integrated. Moreover, the data available to us were also based on the collective requirements of this regulation. It is not feasible to identify the incremental technological and computer costs for each regulation. Although HHS is issuing rules under HIPAA sequentially, affected entities and vendors are bundling services, that is, they have been anticipating the various needs and are designing relatively comprehensive systems as they develop hardware and software. For example, a vendor developing a system for electronic billing would also anticipate and include security features, even in the absence of any regulation. Moreover, a draft of the security rule was first published in 1998. Even though the final is different (and less burdensome), vendors had a reasonable indication of the direction policy would go. Thus, in preparing the electronic transaction rule, we recognized and included costs that might theoretically be associated with security or other HIPAA rules. Hence, some of the "costs" of security have already been accounted for in the Standards for Electronic

Transactions cost estimate (45 CFR parts 160 and 162), which was published in the **Federal Register** on August 17, 2000 (65 FR 50312).

This analysis showed that the combined impact of the Administrative Simplification standards is expected to save the industry \$29.9 billion over 10 years. We are including in each subsequent rule an impact analysis that is specific to the standard or standards in that rule, but the impact analysis will assess only the incremental cost of implementing a given standard over another. Thus, the following discussion contains the impact analysis for the marginal costs of the security standards in this final rule.

The following describes the specific impacts that relate to the security standards. The security of electronic protected health information is, and has been for some time, a basic business requirement that health care entities ignore at their peril. Instances of "hacking" and other security violations may be widely publicized, and can seriously damage an institution's community standing. Appropriate security protections are crucial for encouraging the growth and use of electronic data interchange. The synergistic effect of the employment of the security standards will enhance all aspects of HIPAA's Administrative Simplification requirements. In addition, it is important to recognize that security is not a one-time project, but rather an on-going, dynamic process.

#### *C. Changes From the 1998 Impact Analysis*

The overall impact analysis for Administrative Simplification was first published on May 7, 1998 (63 FR 25320) in the proposed rule for the National Provider Identifier standard (45 CFR part 142), the first of the proposed Administrative Simplification rules. That impact analysis was based on the industry situation at that time, used statistics which were current at that time, and assumed that all of the HIPAA standards would be implemented at roughly the same time, which would permit software changes to be made less expensively. While the original impact analysis represented our best information at that time, we realize that the state of the industry, and of security technology, has changed since 1998. We discuss several of those changes and how they affect the impact of this regulation.

##### *1. Changes in Technology*

The state of technology for health care security has changed since 1998. New



technologies to protect information have been developed over the past several years. As a result, HHS has consulted with the Gartner Group, a leading technology assessment organization, regarding what impact these changes in the industry might have on the expected impact of this regulation. The Gartner analysis indicated that the cost of meeting the requirements of a reasonable interpretation of the security rule in 2002 is probably less than 10 percent higher in 2002 than it was in 1998. This increase is mainly driven by more active threats and increased personnel costs offsetting decreases in technology costs over the past 4 years. However, spending by companies who have anticipated the security rule or who have independently made business decisions to implement security policies and procedures as good business practice(s) has already occurred, and probably will cancel out the increased costs of implementation. Therefore, Gartner expects the cost of complying with the HIPAA security standards to be about the same now as it was in 1998.

## 2. Synchronizing Standards

The timelines for the implementation of the initial HIPAA standards (transactions, identifiers, and security) are no longer closely synchronized. However, we do not believe that this lack of synchronization will have a significant impact on the cost of implementing security. The analysis provided by the Gartner group indicated that implementing security standards is being viewed by entities as a separate task from implementing the transaction standards, and that this is not having a significant impact on costs. As with other HIPAA standards, most current entities will have a 2-year implementation period before compliance with the standards is required. Covered entities will develop their own implementation schedules, and may phase in various security measures over that time period.

## 3. Relationship to Privacy Standards

The publication of the final Privacy Rules (45 CFR parts 160 and 164) on December 28, 2000 in the **Federal Register** (65 FR 82462) and on August 14, 2002 (67 FR 53182) has affected the impact of this regulation significantly. Covered entities must implement the privacy standards by April 14, 2003 (April 14, 2004 for small health plans). The implementation of privacy standards reduces the cost of implementing the security standards in two significant areas.

First, we have made substantial efforts to ensure that the many requirements in

the security standards parallel those for privacy, and can easily be satisfied using the solutions for privacy. Administrative requirements like the need for written policies, responsible officers, and business associate agreements that are already required by the Privacy Rule can also serve to meet the security standards without significant additional cost. The analysis of data flows and data uses that covered entities are doing so as to comply with the Privacy Rule should also serve as the starting point for parallel analysis required by this final rule.

Second, it is likely that covered entities will meet a number of the requirements in the security standards through the implementation of the privacy requirements. For example, in order to comply with the Privacy Rule requirements to make reasonable efforts to limit the access of members of the work force to specified categories of protected health information, covered entities may implement some of the administrative, physical, and technical safeguards that the entity's risk analysis and assessment would require under the Security Rule. E-mail authentication procedures put into place for privacy protection may also meet the security standards, thereby eliminating the need for additional investments to meet these standards. As a result, covered entities that have moved forward in implementing the privacy standards are also implementing security measures at the same time. Since the proposed security standards proposed rule represents the most authoritative guidance now available on the nature of these standards, some entities have been using them to develop their security measures. Those entities should face minimal incremental costs in implementing the final version of these standards.

We are unable to quantify these overlaps, but we believe they may reduce the cost of implementing these security standards. The analysis provided to the HHS by the Gartner Group also stated that compliance with the Privacy Rule will have a moderate effect on the cost of compliance with the Security Rule, reducing it slightly.

## 4. Sensitivity to Security Concerns as a Result of September 11, 2001

In our discussions with the Gartner Group, they indicated that they saw little evidence of increased security awareness in health care organizations as a result of the events of September 11, 2001. However, a survey conducted by Phoenix Health Systems in the winter of 2002 showed that 65 percent of the respondents to the survey

(hospitals, payers, vendors, and clearinghouses) have moderately to greatly increased their attention on overall security. If these organizations have already made investments in security that meet some of the requirements of this rule, it will reduce their added costs of compliance. However, HHS can make no clear statement of the impact of this attention.

## D. Guiding Principles for Standard Selection

The implementation teams charged with designating standards under the statute have defined, with significant input from the health care industry, a set of common criteria for evaluating potential standards. These criteria are based on direct specifications in the HIPAA, the purpose of the law, and principles that support the regulatory philosophy set forth in the E.O. 12866 of September 30, 1993, and the Paperwork Reduction Act of 1995. In order to be designated as such, a standard should do the following:

- Improve the efficiency and effectiveness of the health care system by leading to cost reductions from or improvements in benefits from electronic health care transactions. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden.
- Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses. This principle supports the regulatory goal of cost-effectiveness.
- Be consistent and uniform with the other HIPAA standards (that is, their data element definitions and codes, and their privacy and security requirements) and, secondarily, with other private and public sector health data standards. This principle supports the regulatory goals of consistency and avoidance of incompatibility, and it establishes a performance objective for the standard.
- Have low additional development and implementation costs relative to the benefits of using the standard. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden.
- Be supported by an ANSI-accredited standards developing organization or other private or public organization that would ensure continuity and efficient updating of the standard over time. This principle supports the regulatory goal of predictability.
- Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster. This

principle establishes a performance objective for the standard.

- Be technologically independent of the computer platforms and transmission protocols used in health transactions, except when they are explicitly part of the standard. This principle establishes a performance objective for the standard and supports the regulatory goal of flexibility.

- Be precise and unambiguous but as simple as possible. This principle supports the regulatory goals of predictability and simplicity.

- Keep data collection and paperwork burdens on users as low as is feasible. This principle supports the regulatory goals of cost-effectiveness and avoidance of duplication and burden.

- Incorporate flexibility to adapt more easily to changes in the health care infrastructure (for example, new services, organizations, and provider types) and information technology. This principle supports the regulatory goals of flexibility and encouragement of innovation.

We assessed a wide variety of security standards and guidelines against the principles listed above, with the overall goal of achieving the maximum benefit for the least cost. As we stated in the proposed rule, we found that no single standard for security exists that encompasses all the requirements that were listed in the law. However, we believe that the standards we are adopting in this final rule collectively accomplish these goals.

#### *E. Affected Entities*

##### 1. Health Care Providers

Covered health care providers may incur implementation costs for establishing or updating their security systems. The majority of costs to implement the security standard (purchase and installation of appropriate computer hardware and software, and physical safeguards) would generally be incurred in the initial implementation period for the specific requirements of the security standard. Health care providers that do not conduct electronic transactions for which standards have been adopted are not affected by these regulations.

##### 2. Health Plans

All health plans, as the term is defined in regulation at 45 CFR 160.103, must comply with these security standards. In addition, health plans that engage in electronic health care transactions may have to modify their systems to meet the security standards. Health plans that maintain electronic health information may also have to

modify their systems to meet the security standards. This conversion would have a one-time cost impact on Federal, State, and private plans alike.

We recognize that this conversion process has the potential to cause business disruption of some health plans. However, health plans would be able to schedule their implementation of the security standards and other standards in a way that best fits their needs, as long as they meet the deadlines specified in the HIPAA law and regulations. Moreover, small plans (many of which are employer-sponsored) will have an additional year in which to achieve compliance. Small health plans are defined at 45 CFR 160.103 as health plans with annual receipts of \$5 million or less.

##### 3. Clearinghouses

All health care clearinghouses must meet the requirements of this regulation. Health care clearinghouses would face effects similar to those experienced by health care providers and health plans. However, because clearinghouses represent one way in which providers and plans can achieve compliance, the clearinghouses' costs of complying with these standards would probably be passed along to those entities, to be shared over the entire customer base.

##### 4. System Vendors

Systems vendors that provide computer software applications to health care providers and other billers of health care services would likely be affected. These vendors would have to develop software solutions that would allow health plans, providers, and other users of electronic transactions to protect these transactions and the information in their databases from unauthorized access to their systems. Their costs would also probably be passed along to their customer bases.

#### *F. Factors in Establishing the Security Standard*

##### 1. General Effect

In assessing the impact of these standards, it is first necessary to focus on the general nature of the standards, their scalability, and the fact that they are not dependent upon specific technologies. These factors will make it possible for covered entities to implement them with the least possible impact on resources. Because there is no national security standard in widespread use throughout the industry, adopting any of the candidate standards would require most health care providers, health plans, and health care clearinghouses to at least conduct

an assessment of how their current security measures conform to the new standards. However, we assume that most, if not all, covered entities already have at least some rudimentary security measures in place. Covered entities that identify gaps in their current measures would need to establish or revise their security precautions.

It is also important to note that the standards specify what goals are to be achieved, but give the covered entity some flexibility to determine how to meet those goals. This is different from the transaction standards, where all covered entities must use the exact same implementation guide. With respect to security, covered entities will be able to blend security processes now in place with new processes. This should significantly reduce compliance costs.

Based on our analysis and comments received, the security standards adopted in this rule do not impose a greater burden on the industry than the options we did not select, and they present significant advantages in terms of universality and flexibility.

We understand that some large health plans, health care providers, and health care clearinghouses that currently exchange health information among trading partners may already have security systems and procedures in place to protect the information from unauthorized access. These entities may not incur significant costs to meet the security standards. Large entities that have sophisticated security systems in place may only need minor revisions or updates to their systems to meet the security standards, or indeed, may not need to make any changes in their systems.

While small providers are not likely to have implemented sophisticated security measures, they are also not as likely to need them as larger covered entities. The scalability principle allows providers to adopt measures that are appropriate to their own circumstances.

##### 2. Complexity of Conversion

The complexity of the conversion to the security standards could be significantly affected by the volume of transactions that covered entities transmit and process electronically and the desire to transmit directly or to use the services of a Value Added Network (VAN) or a clearinghouse. If a VAN or clearinghouse is used, some of the conversion activities would be carried out by that organization, rather than by the covered entity. This would simplify conversion for the covered entity, but makes the covered entity dependent on the success of its business associate. The architecture, and specific technology

limitations of existing systems could also affect the complexity of the conversion (for example, certain practice management software that does not contain password protection will require a greater conversion effort than software that has a password protection option already built into it).

### 3. Cost of Conversion

Virtually all providers, health plans, and clearinghouses that transmit or store data electronically have already implemented some security measures and will need to assess existing security, identify areas of risk, and implement additional measures in order to come into compliance with the standards adopted in this rule. We cannot estimate the per-entity cost of implementation because there is no information available regarding the extent to which providers', plans', and clearinghouses' current security practices are deficient. Moreover, some security solutions are almost cost-free to implement (for example, reminding employees not to post passwords on their monitors), while others are not.

Affected entities will have many choices regarding how they will implement security. Some may choose to assess security using in-house staff, while others will use consultants. Practice management software vendors may also provide security consultation services to their customers. Entities may also choose to implement security measures that require hardware and/or software purchases at the time they do routine equipment upgrades.

The security standards we adopt in this rule were developed with considerable input from the health care industry, including providers, health plans, clearinghouses, vendors, and standards organizations. Industry members strongly advocated the flexible approach we adopt in this rule, which permits each affected entity to develop cost-effective security measures appropriate to their particular needs. We believe that this approach will yield the lowest implementation cost to industry while ensuring that electronic protected health information is safeguarded.

All of the nation's health plans (over 2 million) and providers (over 600,000) will need to conduct some level of gap analysis to assess current procedures against the standards. However, we cannot estimate the number of covered entities that would have to implement additional security systems and procedures to meet the adopted standards. Also, we are not able to estimate the number of providers that do not conduct electronic transactions

today but may choose to do so at some future time (these would be entities that send and receive paper transactions and maintain paper records and thus would not be affected). We believe that the security standards represent the minimum necessary for adequate protection of health information in an electronic format and as such should be implemented by all covered entities. As discussed earlier in this preamble, the security requirements are both scalable and technically flexible; and while the law requires each health plan that is not a small plan to comply with the security and electronic signature requirements no later than 24 months after the effective date of the final rule, small plans will be allowed an additional 12 months to comply.

Since we are unable to estimate the number of entities that may need to make changes to meet the security standards, we are also unable to estimate the cost for those entities. However, we believe that the cost of establishing security systems and procedures is a portion of the costs associated with converting to the administrative simplification standards that are required under HIPAA, which are estimated in the previously referenced impact analysis.

This discussion on conversion costs relates only to health plans, health care providers, and health care clearinghouses that are required to implement the security standards. The cost of implementing security systems and procedures for entities that do not transmit, receive, or maintain health information electronically is not a cost imposed by the rule, and thus, is not included in our estimates.

### G. Alternatives Considered

In developing this final rule, the Department considered some alternatives. One alternative was to not issue a final rule. However, this would not meet the Department's obligations under the HIPAA statute. It would also leave the health industry without a set of standards for protecting the security of health information. The vast majority of commenters supported our efforts in developing a set of standards. Thus, we concluded that not publishing a final rule was not in the best interests of the industry and not in the best interests of persons whose medical information will be protected by these measures.

A second alternative was to publish the final rule basically unchanged from the proposed rule. Although most commenters supported the approach of the proposed rule, there were significant objections to the number of required specifications, concerns about the scope

of certain requirements, duplication and ambiguity of some requirements, and the overall complexity of the approach. Based on those comments, it was clear that revisions had to be made. In addition, the proposed rule was developed before the Privacy Rule requirements were developed. Thus, it did not allow for any alignment of requirements between the Privacy and Security standards.

As a result, the Department determined that an approach that modified the proposed rule and aligned the requirements with the Privacy standards was the preferred alternative.

### V. Federalism

Executive Order 13132 of August 4, 1999, Federalism, published in the **Federal Register** on August 10, 1999 (64 FR 43255), requires us to ensure meaningful and timely input by State and local officials in the development of rules that have Federalism implications. Although the proposed rule for security standards was published before the enactment of this Executive Order, the Department consulted with State and local officials as part of an outreach program in the process of developing the proposed regulation. The Department received comments on the proposed rule from State agencies and from entities that conduct transactions with State agencies. Many of these comments were concerned with the burden that the proposed security standards would place on their organizations. In response to those comments, we have modified the security standards to make them more flexible and less burdensome.

In complying with the requirements of part C of Title XI, the Secretary established an interdepartmental team who consulted with appropriate State and Federal agencies and private organizations. These external groups included the NCVHS Workgroup on Standards and Security, the Workgroup for Electronic Data Interchange, the National Uniform Claim Committee, and the National Uniform Billing Committee. Most of these groups have State officials as members. We also received comments on the proposed regulation from these organizations.

In accordance with the provisions of Executive Order 12866, this rule has been reviewed by the Office of Management and Budget.

### List of Subjects

#### 45 CFR Part 160

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health

records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

#### 45 CFR Part 162

Administrative practice and procedure, Health facilities, Health insurance, Hospitals, Medicaid, Medicare, report and recordkeeping requirement.

#### 45 CFR Part 164

Administrative practice and procedure, Health facilities, Health insurance, Hospitals, Medicaid, Medicare, Electronic Information System, Security, Report and recordkeeping requirement.

For the reasons set forth in the preamble, the Department of Health and Human Services amends title 45, subtitle A, subchapter C, parts 160, 162, and 164 as set forth below:

### PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

**Authority:** Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d–1329d–8) as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031 and sec. 264 of Pub. L. 104–191 (42 U.S.C. 1320d–2(note)).

2. In § 160.103, the definitions of “disclosure”, “electronic media”, “electronic protected health information,” “individual,” “organized health care arrangement”, “protected health information,” and “use” are added in alphabetical order to read as follows:

#### § 160.103 Definitions.

\* \* \* \* \*

*Disclosure* means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

\* \* \* \* \*

*Electronic media* means:

(1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media.

Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

*Electronic protected health information* means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

\* \* \* \* \*

*Individual* means the person who is the subject of protected health information.

\* \* \* \* \*

*Organized health care arrangement* means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and

health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

*Protected health information* means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

\* \* \* \* \*

*Use* means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

\* \* \* \* \*

### PART 162—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 is revised to read as follows:

**Authority:** Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

#### § 162.103 [Amended]

2. In § 162.103, the definition of “electronic media” is removed.

### PART 164—SECURITY AND PRIVACY

1. The authority citation for part 164 is revised to read as follows:

**Authority:** Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and 42 U.S.C. 1320d–2 and 1320d–4, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

2. A new § 164.103 is added to read as follows:

#### § 164.103 Definitions.

As used in this part, the following terms have the following meanings:

*Common control* exists if an entity has the power, directly or indirectly,

significantly to influence or direct the actions or policies of another entity.

*Common ownership* exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

*Covered functions* means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

*Health care component* means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(C).

*Hybrid entity* means a single legal entity:

(1) That is a covered entity;  
(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(C).

*Plan sponsor* is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

*Required by law* means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

3. Section 164.104 is revised to read as follows:

#### **§ 164.104 Applicability.**

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

(1) A health plan.  
(2) A health care clearinghouse.  
(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, or other than as

a business associate of a covered entity, the clearinghouse must comply with § 164.105 relating to organizational requirements for covered entities, including the designation of health care components of a covered entity.

4. A new § 164.105 is added to read as follows:

#### **§ 164.105 Organizational requirements.**

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*

(i) *Application of other provisions.* In applying a provision of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

(A) A reference in such provision to a "covered entity" refers to a health care component of the covered entity;

(B) A reference in such provision to a "health plan," "covered health care provider," or "health care clearinghouse," refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;

(C) A reference in such provision to "protected health information" refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and

(D) A reference in such provision to "electronic protected health information" refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity.

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this section and subparts C and E of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information

with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) A component that is described by paragraph (a)(2)(iii)(C)(2) of this section does not use or disclose protected health information that it creates or receives from or on behalf of the health care component in a way prohibited by subpart E of this part;

(D) A component that is described by paragraph (a)(2)(iii)(C)(2) of this section that creates, receives, maintains, or transmits electronic protected health information on behalf of the health care component is in compliance with subpart C of this part; and

(E) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with subpart E of this part.

(B) The covered entity is responsible for complying with § 164.316(a) and § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this section and subparts C and E of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates a health care component or components, it must include any component that would meet the definition of covered entity if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs:

(1) Covered functions; or  
(2) Activities that would make such component a business associate of a

component that performs covered functions if the two components were separate legal entities.

(b)(1) *Standard: Affiliated covered entities.* Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of subparts C and E of this part.

(1) *Implementation specifications:*

(i) *Requirements for designation of an affiliated covered entity.*

(A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of subparts C and E of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements.* An affiliated covered entity must ensure that:

(A) The affiliated covered entity's creation, receipt, maintenance, or transmission of electronic protected health information complies with the applicable requirements of subpart C of this part;

(B) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of subpart E of this part; and

(C) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with § 164.308(a)(4)(ii)(A) and § 164.504(g), as applicable.

(c)(1) *Standard: Documentation.* A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section.

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation as required by paragraph (c)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

5. A new subpart C is added to part 164 to read as follows:

#### **Subpart C—Security Standards for the Protection of Electronic Protected Health Information**

Sec.

164.302 Applicability.

164.304 Definitions.

164.306 Security standards: General rules.

164.308 Administrative safeguards.

164.310 Physical safeguards.

164.312 Technical safeguards.

164.314 Organizational requirements.

164.316 Policies and procedures and documentation requirements.

164.318 Compliance dates for the initial implementation of the security standards.

#### **Appendix A to Subpart C of Part 164—Security Standards: Matrix**

**Authority:** 42 U.S.C. 1320d–2 and 1320d–4.

#### **§ 164.302 Applicability.**

A covered entity must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information.

#### **§ 164.304 Definitions.**

As used in this subpart, the following terms have the following meanings:

*Access* means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to “access” as used in this subpart, not as used in subpart E of this part.)

*Administrative safeguards* are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information.

*Authentication* means the corroboration that a person is the one claimed.

*Availability* means the property that data or information is accessible and useable upon demand by an authorized person.

*Confidentiality* means the property that data or information is not made available or disclosed to unauthorized persons or processes.

*Encryption* means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key.

*Facility* means the physical premises and the interior and exterior of a building(s).

*Information system* means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

*Integrity* means the property that data or information have not been altered or destroyed in an unauthorized manner.

*Malicious software* means software, for example, a virus, designed to damage or disrupt a system.

*Password* means confidential authentication information composed of a string of characters.

*Physical safeguards* are physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

*Security or Security measures* encompass all of the administrative, physical, and technical safeguards in an information system.

*Security incident* means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

*Technical safeguards* means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

*User* means a person or entity with authorized access.

*Workstation* means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.

#### **§ 164.306 Security standards: General rules.**

(a) *General requirements.* Covered entities must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity creates, receives, maintains, or transmits.

(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

(3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.

(4) Ensure compliance with this subpart by its workforce.

(b) *Flexibility of approach.*

(1) Covered entities may use any security measures that allow the covered entity to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity.

(ii) The covered entity's technical infrastructure, hardware, and software security capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to electronic protected health information.

(c) *Standards.* A covered entity must comply with the standards as provided in this section and in § 164.308, § 164.310, § 164.312, § 164.314, and § 164.316 with respect to all electronic protected health information.

(d) *Implementation specifications.*

In this subpart:

(1) Implementation specifications are required or addressable. If an implementation specification is required, the word "Required" appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word "Addressable" appears in parentheses after the title of the implementation specification.

(2) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes required implementation specifications, a covered entity must implement the implementation specifications.

(1) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes addressable implementation specifications, a covered entity must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting the entity's electronic protected health information; and

(ii) As applicable to the entity—

(A) Implement the implementation specification if reasonable and appropriate; or

(B) If implementing the implementation specification is not reasonable and appropriate—

(1) Document why it would not be reasonable and appropriate to implement the implementation specification; and

(2) Implement an equivalent alternative measure if reasonable and appropriate.

(e) *Maintenance.* Security measures implemented to comply with standards and implementation specifications adopted under § 164.105 and this subpart must be reviewed and modified as needed to continue provision of reasonable and appropriate protection of electronic protected health information as described at § 164.316.

#### **§ 164.308 Administrative safeguards.**

(a) A covered entity must, in accordance with § 164.306:

(1)(i) *Standard: Security management process.* Implement policies and procedures to prevent, detect, contain, and correct security violations.

(ii) *Implementation specifications:*

(A) *Risk analysis* (Required). Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

(B) *Risk management* (Required). Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

(C) *Sanction policy* (Required). Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.

(D) *Information system activity review* (Required). Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.

(3)(i) *Standard: Workforce security.* Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

(ii) *Implementation specifications:*

(A) *Authorization and/or supervision* (Addressable). Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

(B) *Workforce clearance procedure* (Addressable). Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

(C) *Termination procedures* (Addressable). Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4)(i) *Standard: Information access management.* Implement policies and procedures for authorizing access to

electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

(ii) *Implementation specifications:*

(A) *Isolating health care clearinghouse functions* (Required). If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

(B) *Access authorization* (Addressable). Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

(C) *Access establishment and modification* (Addressable). Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

(5)(i) *Standard: Security awareness and training.* Implement a security awareness and training program for all members of its workforce (including management).

(ii) *Implementation specifications.* Implement:

(A) *Security reminders* (Addressable). Periodic security updates.

(B) *Protection from malicious software* (Addressable). Procedures for guarding against, detecting, and reporting malicious software.

(C) *Log-in monitoring* (Addressable). Procedures for monitoring log-in attempts and reporting discrepancies.

(D) *Password management* (Addressable). Procedures for creating, changing, and safeguarding passwords.

(6)(i) *Standard: Security incident procedures.* Implement policies and procedures to address security incidents.

(ii) *Implementation specification: Response and Reporting* (Required). Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.

(7)(i) *Standard: Contingency plan.* Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*



(A) *Data backup plan* (Required). Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

(B) *Disaster recovery plan* (Required). Establish (and implement as needed) procedures to restore any loss of data.

(C) *Emergency mode operation plan* (Required). Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

(D) *Testing and revision procedures* (Addressable). Implement procedures for periodic testing and revision of contingency plans.

(E) *Applications and data criticality analysis* (Addressable). Assess the relative criticality of specific applications and data in support of other contingency plan components.

(8) *Standard: Evaluation*. Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.

(b)(1) *Standard: Business associate contracts and other arrangements*. A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a) that the business associate will appropriately safeguard the information.

(2) This standard does not apply with respect to—

(i) The transmission by a covered entity of electronic protected health information to a health care provider concerning the treatment of an individual.

(ii) The transmission of electronic protected health information by a group health plan or an HMO or health insurance issuer on behalf of a group health plan to a plan sponsor, to the extent that the requirements of § 164.314(b) and § 164.504(f) apply and are met; or

(iii) The transmission of electronic protected health information from or to other agencies providing the services at § 164.502(e)(1)(ii)(C), when the covered entity is a health plan that is a government program providing public

benefits, if the requirements of § 164.502(e)(1)(ii)(C) are met.

(3) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.314(a).

(4) *Implementation specifications: Written contract or other arrangement* (Required). Document the satisfactory assurances required by paragraph (b)(1) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

#### **§ 164.310 Physical safeguards.**

A covered entity must, in accordance with § 164.306:

(a)(1) *Standard: Facility access controls*. Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(2) *Implementation specifications:*

(i) *Contingency operations* (Addressable). Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

(ii) *Facility security plan* (Addressable). Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

(iii) *Access control and validation procedures* (Addressable). Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

(iv) *Maintenance records* (Addressable). Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks).

(b) *Standard: Workstation use*. Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.

(c) *Standard: Workstation security*. Implement physical safeguards for all workstations that access electronic

protected health information, to restrict access to authorized users.

(d)(1) *Standard: Device and media controls*. Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.

(2) *Implementation specifications:*

(i) *Disposal* (Required). Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored.

(ii) *Media re-use* (Required).

Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.

(iii) *Accountability* (Addressable). Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

(iv) *Data backup and storage* (Addressable). Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

#### **§ 164.312 Technical safeguards.**

A covered entity must, in accordance with § 164.306:

(a)(1) *Standard: Access control*. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).

(2) *Implementation specifications:*

(i) *Unique user identification* (Required). Assign a unique name and/or number for identifying and tracking user identity.

(ii) *Emergency access procedure* (Required). Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

(iii) *Automatic logoff* (Addressable). Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

(iv) *Encryption and decryption* (Addressable). Implement a mechanism to encrypt and decrypt electronic protected health information.

(b) *Standard: Audit controls*.

Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.

(c)(1) *Standard: Integrity*. Implement policies and procedures to protect



electronic protected health information from improper alteration or destruction.

(2) *Implementation specification:*

*Mechanism to authenticate electronic protected health information*

(Addressable). Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.

(d) *Standard: Person or entity authentication.* Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

(e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

(2) *Implementation specifications:*

(i) *Integrity controls* (Addressable). Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.

(ii) *Encryption* (Addressable). Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

**§ 164.314 Organizational requirements.**

(a)(1) *Standard: Business associate contracts or other arrangements.*

(i) The contract or other arrangement between the covered entity and its business associate required by § 164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications* (Required).

(i) *Business associate contracts.* The contract between a covered entity and a business associate must provide that the business associate will—

(A) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the

confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the covered entity as required by this subpart;

(B) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it;

(C) Report to the covered entity any security incident of which it becomes aware;

(D) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(ii) *Other arrangements.*

(A) When a covered entity and its business associate are both governmental entities, the covered entity is in compliance with paragraph (a)(1) of this section, if—

(1) It enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (a)(2)(i) of this section; or

(2) Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (a)(2)(i) of this section.

(B) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in § 160.103 of this subchapter to a covered entity, the covered entity may permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of paragraph (a)(2)(i) of this section, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (a)(2)(ii)(A) of this section, and documents the attempt and the reasons that these assurances cannot be obtained.

(C) The covered entity may omit from its other arrangements authorization of the termination of the contract by the covered entity, as required by paragraph (a)(2)(i)(D) of this section if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(b)(1) *Standard: Requirements for group health plans.* Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to

§ 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

(2) *Implementation specifications* (Required). The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to—

(i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan;

(ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures;

(iii) Ensure that any agent, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

(iv) Report to the group health plan any security incident of which it becomes aware.

**§ 164.316 Policies and procedures and documentation requirements.**

A covered entity must, in accordance with § 164.306:

(a) *Standard: Policies and procedures.* Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

(b)(1) *Standard: Documentation.*

(i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit* (Required). Retain the documentation required by paragraph (b)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

(ii) *Availability* (Required). Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

(iii) *Updates* (Required). Review documentation periodically, and update

as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

**§ 164.318 Compliance dates for the initial implementation of the security standards.**

(a) *Health plan.*

(1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.

(2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006.

(b) *Health care clearinghouse.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 20, 2005.

(c) *Health care provider.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

**Appendix A to Subpart C of Part 164—Security Standards: Matrix**

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
<b>Administrative Safeguards</b>		
Security Management Process .....	164.308(a)(1)	Risk Analysis (R) Risk Management (R) Sanction Policy (R) Information System Activity Review (R)
Assigned Security Responsibility .....	164.308(a)(2)	(R)
Workforce Security .....	164.308(a)(3)	Authorization and/or Supervision (A) Workforce Clearance Procedure Termination Procedures (A)
Information Access Management .....	164.308(a)(4)	Isolating Health care Clearinghouse Function (R) Access Authorization (A) Access Establishment and Modification (A)
Security Awareness and Training .....	164.308(a)(5)	Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A) Password Management (A)
Security Incident Procedures .....	164.308(a)(6)	Response and Reporting (R)
Contingency Plan .....	164.308(a)(7)	Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A) Applications and Data Criticality Analysis (A)
Evaluation .....	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
<b>Physical Safeguards</b>		
Facility Access Controls .....	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)
Workstation Use .....	164.310(b)	(R)
Workstation Security .....	164.310(c)	(R)
Device and Media Controls .....	164.310(d)(1)	Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)
<b>Technical Safeguards (see § 164.312)</b>		
Access Control .....	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls .....	164.312(b)	(R)
Integrity .....	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication .....	164.312(d)	(R)
Transmission Security .....	164.312(e)(1)	Integrity Controls (A) Encryption (A)

**§164.500 [Amended]**

6. § In 164.500(b)(1)(iv), remove the words “including the designation of health care components of a covered entity”.

**§ 165.501 [Amended]**

7. In §164.501, the definitions of the following terms are removed: *Covered functions*, *Disclosure*, *Individual*, *Organized health care arrangement*, *Plan sponsor Protected health information*, *Required by law*, and *Use*.

**§ 164.504 [Amended]**

8. In §164.504, the following changes are made:

a. The definitions of the following terms are removed: *Common control*, *Common ownership*, *Health care component*, and *Hybrid entity*.

b. Paragraphs (b) through (d) are removed and reserved.

**Authority:** Sections 1173 and 1175 of the Social Security Act (42 U.S.C. 1329d-2 and 1320-4).

Dated: January 13, 2003.

**Tommy G. Thompson,**  
Secretary.

[FR Doc. 03-3877 Filed 2-13-03; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 162

[CMS-0003-F and CMS-0005-F]

RINs 0938-AK64 and 0938-AK76

### Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rule.

**SUMMARY:** In this final rule, we respond to public comments received and finalize provisions applicable to electronic data transaction standards from two related proposed rules published in the May 31, 2002, **Federal Register**. We are also adopting proposed modifications to implementation specifications for health care entities and others. In addition, we are adopting modifications to implementation specifications for several electronic transaction standards that were omitted from the May 31, 2002, proposed rules.

**EFFECTIVE DATES:** These regulations are effective on March 24, 2003. The incorporation by reference of certain publications listed in this final rule is

approved by the Director of the Federal Register as of March 24, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Gladys Wheeler, (410) 786-0273.

**SUPPLEMENTARY INFORMATION:**

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### I. Background

#### A. Electronic Data Interchange

Electronic data interchange (EDI) refers to the electronic transfer of information in a standard format between trading partners. When compared with paper submissions, EDI can substantially lessen the time and costs associated with receiving, processing, and storing documents. The use of EDI can also eliminate inefficiencies and streamline processing tasks, which can in turn result in less administrative burden, lower operating costs, and improved overall data quality.

The health care industry recognizes the benefits of EDI, and many entities in the industry have developed proprietary EDI formats. However, with the increasing use of health care EDI standards, the lack of common, industry-wide standards has emerged as a major obstacle to realizing potential efficiency and savings.

#### B. Statutory and Regulatory Background

##### 1. Statutory Background

The Congress included provisions to address the need for developing a consistent framework for electronic transactions and other administrative simplification issues in the Health

Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, which became law on August 21, 1996. Through subtitle F of title II of that statute, the Congress added to title XI of the Social Security Act (the Act) a new part C, titled “Administrative Simplification.” The purpose of this part is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care system in general, by encouraging the development of standards and requirements to enable the electronic exchange of certain health information.

Part C of title XI consists of sections 1171 through 1179 of the Act. Section 1172 of the Act and the implementing regulations make any standard adopted under part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit any health information in electronic form in connection with a transaction covered by 45 CFR part 162.

In general, section 1172 of the Act requires any standard adopted by the Secretary of Health and Human Services (the Secretary) under this part to be a standard that has been developed, adopted, or modified by a standard setting organization (SSO). The Secretary may adopt a different standard if the standard will substantially reduce administrative costs to providers and health plans compared to the alternatives, and the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, U.S.C.

Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt standards. In the case of a standard that is developed, adopted, or modified by an SSO, the SSO must consult with the following Data Content Committees (DCCs) in the course of the development, adoption, or modification of the standard: The National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). In the case of any other standard, the Secretary is required to consult with each of the above-named groups before adopting the standard and must also comply with the provisions of section 1172(f) of the Act regarding consultation with the National Committee on Vital and Health Statistics (NCVHS).

Section 1173 of the Act requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable the electronic exchange of health information. Section

1173 lists the transactions and sets out requirements for the specific standards the Secretary is to adopt: Unique health identifiers, code sets, security standards, electronic signatures, and transfer of information among health plans.

Section 1174 of the Act permits the Secretary to make modifications to any established standard after the first year, but not more frequently than once every 12 months. It permits the Secretary to modify an initial standard at any time during the first year of adoption, if he determines that the modification is necessary to permit compliance with the standard.

Section 1175 of the Act requires that covered entities comply with modifications to standards or implementation specifications made after initial adoption by stating that the Secretary will designate a compliance date that may not be earlier than 180 days after the modification is adopted.

We discussed HIPAA-specific legislation in greater detail in the Transactions Rule (65 FR 50312) and the December 28, 2000, final rule, Standards for Privacy of Individually Identifiable Health Information" (65 FR 82462) (the Privacy Rule). Rather than repeating the discussion in its entirety here, we refer the reader to those documents for further information about EDI and the statutory background.

## 2. Regulatory Background

On May 7, 1998 (63 FR 25272), the Secretary proposed Standards for Electronic Transactions and Code Sets. On August 17, 2000, the final rule on Standards for Electronic Transactions and Code Sets was published in the **Federal Register** (65 FR 50312). In the August 17, 2000, final rule, (the Transactions Rule), the Secretary adopted standards for eight electronic transactions and six code sets. The transactions are:

- Health Care Claims or Equivalent Encounter Information;
- Eligibility for a Health Plan;
- Referral Certification and Authorization;
- Health Care Claim Status;
- Enrollment and Disenrollment in a Health Plan;
- Health Care Payment and Remittance Advice;
- Health Plan Premium Payments;

and

- Coordination of Benefits.
- The code sets are: International Classification of Diseases, 9th Edition, Clinical Modification, Volumes 1 and 2;
- International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures;
  - National Drug Codes;

- Code on Dental Procedures and Nomenclature;
- Health Care Financing Administration Common Procedure Coding System; and
- Current Procedural Terminology, 4th Edition.

This final rule adopts modifications to the August 17, 2000 transaction and code set standards.

## 3. Statutory Requirements and Implementation Instructions for EDI Standards

Section 1172(d) of the Act requires the Secretary to establish specifications for implementing each adopted standard. However, because the implementation instructions are voluminous, they were incorporated by reference in the Transactions Rule. This approach, to incorporate by reference, is commonly used by the **Federal Register** when external organizations are tasked with developing standards that are subsequently adopted as national standards. We are using this approach in this final rule to adopt modifications to the specified standards that were proposed in the May 31, 2002 proposed rules, CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050).

### C. Designated Standard Maintenance Organization (DSMO) Process

In our May 31, 2002, proposed rule, CMS-0005-P (67 FR 38050), we described in detail the process used by the Designated Standard Maintenance Organization (DSMO) Memorandum of Understanding (MOU) for receiving, managing and processing requested changes to the adopted standards. CMS-0005-P identified the six DSMOs and explained that we had used the process specified in the MOU to develop the proposed modifications to standards adopted in regulations. For ease of reference, we have included the DSMO names and respective websites below. Both of the SSOs (Accredited Standards Committee ASC X12N and the National Council for Prescription Drug Programs (NCPDP)) that develop standards adopted by the Secretary are DSMOs.

### DSMO Names and Web site Addresses

- Accredited Standards Committee X12N (ASC X12N) (<http://www.x12.org>).
- Health Level Seven, Inc. (HL 7) (<http://www.hl7.org>).
- National Council for Prescription Drug Programs (NCPDP) (<http://www.ncdp.org>).
- National Uniform Billing Committee (NUBC) (<http://www.nubc.org>).
- National Uniform Claim Committee (NUCC) (<http://www.nucc.org>).

- Dental Content Committee of the American Dental Association (<http://www.ada.org>).

For additional information regarding the DSMO change request process, see the MOU document, which is available at: [www.hipaa-dsmo.org/mou.pdf](http://www.hipaa-dsmo.org/mou.pdf).

As we stated in CMS-0005-P (67 FR 38050), a significant number of change requests were submitted through the DSMO process after the initial EDI transaction standards were adopted in the regulations. Many of those change requests were for changes that were considered by the submitters to be essential to permit initial implementation of the standards throughout the entire healthcare industry. Those change requests addressed specific details or elements within the implementation specifications.

Changes considered essential for implementation of the adopted standards were reviewed by the DSMOs and assigned "fast track" status for development within the authority of the DSMO process. (Other changes that were not considered essential are going through the general change request management process set forth in the MOU.) As specified in the MOU, the DSMOs then presented those changes deemed essential for initial implementation to the NCVHS. The NCVHS held public hearings on those proposed changes (transcripts of those hearings are available at <http://www.ncvhs.hhs.gov>). The NCVHS recommended that the Secretary adopt all of the changes proposed by the DSMOs as modifications to the national standards. Those changes are reflected in the modifications to standards that are adopted by this final rule.

## II. Provisions of the May 31, 2002, Proposed Rules

In the May 31, 2002, **Federal Register**, we published two proposed rules, CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050). The two proposed rules proposed to adopt as regulations certain modifications to adopted standards.

The first proposed rule is entitled "Modifications to Standards for Electronic Transactions and Code Sets" (67 FR 38044). Hereafter, for the purposes of this final rule, we refer to this proposed rule as CMS-0003-P. CMS-0003-P contained several proposed modifications that pertained exclusively to revisions to certain electronic data interchange (EDI) standards currently in effect for retail pharmacy transactions and a repeal of the designation of National Drug Codes (NDC) as the standard medical data code

set for reporting drugs and biologics on non-retail pharmacy standard transactions.

The second proposed rule is entitled "Modifications to Transactions and Code Set Standards for Electronic Transactions" (67 FR 38050). Hereafter, for the purposes of this final rule, we refer to this proposed rule as CMS-0005-P. CMS-0005-P addressed proposals to adopt limited technical changes to implementation specifications for the transaction standards that were deemed necessary to implement industry-wide EDI standards.

Because both of these proposed rules proposed modifications or technical changes to standards that the Secretary of Health and Human Services (the Secretary) adopted in the August 17, 2000, final rule entitled "Health Insurance Reform: Standards for Electronic Transactions" (65 FR 50312), we are combining them in this final rule. Hereafter, for the purposes of this final rule, we refer to the August 17, 2000, final rule as the "Transactions Rule."

Specifically, in CMS-0003-P, we proposed to adopt the following:

- The National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, for retail pharmacy drug claims, eligibility, and coordination of benefits transactions, to replace the earlier version (Version 1.0) that we had previously adopted in error. In this final rule, we refer to this proposed standard as the "NCPDP Batch Implementation Guide Version 1.1."

- The National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the referral certification and authorization transaction, to replace the ASC X12N 278—Health Care Services Review standard. In this final rule, we refer to these two proposed standards as the "NCPDP Batch Implementation Guide Version 1.1" and the "NCPDP Telecommunication Guide Version 5.1," respectively.

- ASC X12N 835—Health Care Claim Payment/Advice for the retail pharmacy health care payment and remittance advice transaction, to replace the NCPDP Batch Standard Batch Implementation Guide Version 1.0 and the NCPDP Telecommunication Guide Version 5.1.

- We also proposed to repeal the adoption of the National Drug Code (NDC) as the standard for reporting drugs and biologics on all transactions except retail pharmacy transactions, also termed "non-retail pharmacy" transactions below. This repeal would result in there being no standard in place for reporting drugs and biologics on non-retail pharmacy transactions.

### III. Analysis of, and Responses to, Comments on the Proposed Rules

In response to the May 31, 2002, publication of the two proposed rules, we received over 300 timely public comments. The comments came from a variety of sources, including health care associations and societies, entities named in the HIPAA legislation, health plans, DSMOs, health care providers, Federal health plans, and private individuals.

Our process of reviewing and associating like comments identified areas of the proposed rules that required additional review in terms of their effect on policy, consistency, or clarity of the modifications to the standards, and areas that were technical and specifically related to the implementation specifications. We consulted with the DSMOs on technical comments that related specifically to the implementation specifications.

We present comments and responses generally in the order in which the proposals appeared in the May 31, 2002 proposed rules. We begin with comments and responses about the compliance dates, and continue with comments and responses on the proposals in CMS-0003-P (67 FR 38044), and those in CMS-0005-P (67 FR 38050).

#### A. Compliance Date

Under the Act, as reflected in § 160.104, the Secretary establishes the compliance date for modifications to standards. The compliance date must not be earlier than 180 days after the effective date of the adoption of the modification. We had not proposed a compliance date in the proposed rules.

The Administrative Simplification Compliance Act (ASCA) (Pub. L. 107-105) was enacted on December 27, 2001. This law provided an extension to the compliance date adopted in the Transactions Rule (65 FR 50312) for covered entities that submitted, by October 15, 2002, plans to the Secretary indicating how they will come into compliance by October 16, 2003. Small health plans were not provided with an extension opportunity, but also have a compliance date of October 16, 2003. Because this final rule is modifying

standards that are currently in effect and with which compliance is otherwise required, ASCA is relevant. ASCA did not address its effect on those covered entities otherwise required to come into compliance by October 16, 2002, or how modifications to standards were to be implemented.

*Comment:* Numerous commenters expressed support for the adoption of the modifications and stressed the urgency for implementing the modifications to meet compliance by October 16, 2003. We received some comments requesting clarification for the processing of non-compliant claims submitted before the compliance date of October 16, 2003, but processed after October 16, 2003. A few commenters recommended extensions of up to 90 days after October 16, 2003, to allow for an orderly migration to the adopted modifications. The modifications to the transactions are referred to collectively in this final rule as the "Addenda." One commenter suggested that the Department of Health and Human Services (HHS) establish a transition period as a precedent for implementation of future transaction standard versions, such as ASC X12N 4050. One commenter asked for clarification as to whether the ASCA extension was for 1 year after the 180-day adoption period for the Addenda. We received a few comments concerning the impact that publication of this rule would have on the April 2003 ASCA HIPAA testing requirements. One commenter suggested that HHS adopt the ASC X12N 4050 Version implementation specifications, instead of the ASC X12N 4010 Addenda.

*Response:* The effective date for this final rule is 30 days after the date of publication in the **Federal Register**. Standards are adopted and implementation specifications are established as of the effective date of this final rule. Trading partner agreements should determine the processing requirements for non-compliant claims submitted by covered entities that have requested a compliance extension for the period between October 16, 2002, and October 16, 2003.

To avoid confusion over the interaction between the compliance dates for the original rule, the compliance dates for these modifications, and the ASCA extension dates, we have revised the regulations text at 45 CFR 162.900. Covered entities, other than small health plans, that have timely submitted a compliance plan will be required to come into compliance with the Transactions Rule as amended

by these modifications no later than October 16, 2003. ASCA, however, complicates the compliance picture greatly.

Hundreds of thousands of entities, including numerous large health plans, have obtained 1-year extensions under ASCA. Consequently, those entities, as well as small health plans, are not required to conduct covered transactions in standard form until October 16, 2003, as clarified at section 162.900. Section 162.923 (a) provides that covered entities must conduct transactions as standard transactions, except as otherwise provided in part 162. Thus, we interpret § 162.923(a), when read with section 162.900, to mean that if both sides to a transaction are not required to conduct it in standard form (that is, if one side is required to conduct the transaction in standard form but the other side is not), neither side is required to conduct it in standard form, provided that the requirements to § 162.925 do not apply. Thus, for example, even where a covered health care provider failed to submit a compliance plan, it would not be required to comply with the Transactions Rule with respect to the covered transactions which it actually conducts during the period of October 16, 2002, through October 15, 2003, insofar as the transactions are with a health plan that is not required to comply during this period because it (1) has obtained a 1-year extension under ASCA, or (2) is a small health plan. Similarly, a health plan that is subject to the October 16, 2002, compliance date would not be required to conduct coordination of benefits in standard form with another health plan, if the latter plan was not conducting the transaction in standard form because it (1) has obtained a 1-year extension under ASCA, or (2) is a small health plan.

Further, even where compliance is required (that is, the October 16, 2002, compliance date applies to both sides to the covered transaction and neither covered entity submitted a compliance plan), we recognize that the modifications adopted as a result of CMS-0003-P and CMS-0005-P are necessary to permit the transactions covered by these proposed rules to be conducted in standard form, and that such transactions could not feasibly be required before the compliance date for the modifications in this final rule, October 16, 2003. We will not invoke our authority to penalize noncompliance with standards that our own delay in issuing this final rule has made infeasible.

With respect to the remaining universe of transactions with which compliance would otherwise be required, as between covered entities that did not submit compliance plans, we recognize that covered entities may find it difficult to determine which of their trading partners must also comply in this interim year, and may in good faith mistakenly assume that the other side to a transaction is exempted from the compliance requirement. We also note that the failure to issue the modifications below earlier has made testing of the standards between trading partners difficult, if not infeasible. Also, complying with the unmodified standards would result in implementation problems and divert resources from complying with the modified standards, which will become the industry standard in October 2003.

In light of these considerations, we have come to two decisions. First, we are affording those covered entities that have a present compliance obligation the opportunity to comply with either the unmodified transaction standards or the modified transaction standards in this interim 1-year period. This policy is reflected in § 162.900(c)(1) below. Second, we intend to take into account the numerous obstacles to compliance that exist and will work with covered entities to bring them into compliance during this interim period, through among other things, corrective action plans. We will reserve our authority to penalize noncompliance for those cases of noncompliance where such voluntary efforts fail or where covered entities fail to make reasonable efforts to come into compliance.

The modifications proposed in the two proposed rules published on May 31, 2002, and promulgated in this final rule were expressly designed and adopted to assist compliance with the standards. These modifications will, no doubt, greatly facilitate the process of becoming compliant.

We accordingly believe that publication of this final rule and the adopted revisions in the Addenda permit sufficient time to meet the ASCA testing requirements for April 2003, and the October 16, 2003, compliance date. Trading partner agreements should determine the processing requirements for non-compliant claims submitted by covered entities that have requested a compliance extension until October 16, 2003.

ASCA provided the option to obtain a 1-year extension to covered entities, excluding small health plans. We have no statutory authority to extend the compliance dates beyond this 1-year extension period. We also believe that

extending the compliance dates further, were we permitted to do so, would place additional and unacceptable burdens on covered entities that are compliant on schedule.

With regard to adopting the 4050 Version of the Implementation Guides, it is our understanding that the healthcare industry is in the midst of implementing the 4010 Version of the Implementation Guides. Adopting a new version of the guides would unfairly burden those who are completing the testing and implementation of the 4010 Version. Also, when covered entities are fully functional with the 4010 Version and its Addenda, they will have a better opportunity to assess improvements for future versions of the Implementation Guides.

#### *B. Responses to Comments on CMS-0003-P (67 FR 38044)*

##### *1. Retail Pharmacy Batch Transactions*

In CMS-0003-P, we proposed that the Secretary adopt the NCPDP Batch Implementation Guide Version 1.1, supporting NCPDP Telecommunication Guide Version 5.1 for the NCPDP Data Record in the Detail Data Record. Adopting this standard would enable covered entities conducting retail pharmacy drug claims or equivalent encounter information, eligibility for a health plan, and coordination of benefits transactions to be able to submit transactions in batches.

We had intended to adopt the NCPDP Batch Implementation Guide Version 1.1 in the Transactions Rule. However, an oversight resulted in the adoption of a batch version that was not the equivalent companion to the telecommunication standard that we adopted. The oversight, if not corrected, would mean that retail pharmacy transactions could not be batched. They would instead have to be submitted individually.

*Comment:* One commenter observed that the NCPDP Telecommunication Guide Version 5.1 did not contain all the data elements required for their health plan to process the claim.

*Response:* The NCPDP, which is the SSO that developed the NCPDP Telecommunication Guide Version 5.1, has certified for us that the standard does allow the reporting of information necessary to process retail pharmacy drug claims. Because of the widespread support for this transaction standard as expressed in the public comments received and because of the assurance that essential data elements are present in the NCPDP Telecommunication Guide Version 5.1, the Secretary is

adopting that standard in this final rule. That standard and the NCPDP Batch Implementation Guide Version 1.1 are adopted for retail pharmacy drug claims or equivalent encounter information (§ 162.1102), eligibility for a health plan (§ 162.1202), and coordination of benefits (§ 162.1802).

## 2. Referral Certification and Authorization Transaction

We proposed to adopt the NCPDP Batch Implementation Guide Version 1.1, supporting the NCPDP Telecommunication Guide Version 5.1, for the NCPDP Data Record in the Detail Data Record, as the standard for the referral certification and authorization transaction. Adopting this standard would enable the reporting of all the data that are critical to retail pharmacy prior authorization transactions. This standard would replace the ASC X12N 278—Request for Review and Response Transaction, which, according to information we received from the retail pharmacy industry, does not support data that are critical to retail pharmacy prior authorization transactions. The ASC X12N standards development process for modifying standards could not be completed in time to change the standard to make it useable for retail pharmacy prior authorization transactions before the October 16, 2002, compliance date for the Transactions Rule. The NCPDP standard adequately supports this transaction for retail pharmacy, is currently in widespread industry use, and the revised 278 would not present significant advantages over it. We expect the NCPDP will continue to be the standard in the future. This modification would not affect the standard for dental, professional, and institutional referral certification and authorization transactions, which is the ASC X12N 278 standard transaction.

*Comment:* One commenter asked if the standard would apply only to retail pharmacy drug referral certifications and authorizations. The commenter believed it should apply to all retail pharmacy referral certifications and authorizations, including supplies.

*Response:* The standard would only apply to retail pharmacy drug referral certification and authorization transactions.

All of the commenters supported this proposal. We are adopting in this final rule the NCPDP Batch Implementation Guide Version 1.1 that supports the NCPDP Telecommunication Version 5.1, as the referral certification and authorization transaction standard for all retail pharmacy drug claim

certification and authorization transactions (§ 162.1302).

## 3. Health Care Claim Payment and Remittance Advice Transaction

In the May 31, 2002, proposed rule, we proposed to adopt the ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, and any adopted modifications to it, for retail pharmacy transactions. Adopting this standard would enable health plans to generate HIPAA-compliant remittance advice transactions for pharmacies. The NCPDP standard format adopted by the Transactions Rule would not have the capability of generating a per claim remittance advice transaction.

*Comment:* Several commenters pointed out that the proposed provisions in § 162.1602 list “dental, professional, and institutional health care claims and remittance advice” and recommended adding “retail pharmacy” to that list, or removing the list entirely.

*Response:* We agree with these comments and note that the ASC X12N 835 is currently the standard for health care claims payment and remittance advice for dental, professional, and institutional claims. Adopting the ASC X12N 835 for retail pharmacy health care claims payment and remittance advice would mean that it would be the standard for all types of health care claims. Therefore, there would be no need to include a list that specifies the applicable claims transactions. In this final rule, we are removing the list at § 162.1602.

*Comment:* A commenter suggested that pharmacies should not have to implement both ASC X12N and NCPDP standards at this time, and that at some point after the compliance date, future harmonization may be practical.

*Response:* Many entities today use the formats of more than one Standards Development Organization (SDO) for the electronic transactions they conduct. In addition, many entities are preparing to do so to comply with regulations. In this situation, however, the NCPDP format does not adequately support the health care payment and remittance advice transaction.

The majority of commenters who submitted comments on this proposal supported the adoption of the ASC X12N 835 for this standard, including three major pharmacy organizations. Therefore, in this final rule, we are adopting the ASC X12N 835—Health Care Claim Payment/Advice as the standard for retail pharmacy health care payment and remittance advice (§ 162.1602).

## 4. National Drug Codes (NDC) Code Set

In CMS–0003–P, we proposed to repeal the National Drug Codes (NDC) as the standard medical data code set for reporting drugs and biologics in institutional, professional, and dental claims (that is, in non-retail pharmacy drug claims). (Drugs are not reported in the adopted standard dental claim transaction.) This repeal would leave no standard in place for use in reporting drugs and biologics on those claims. A health plan could require a provider to use any one of the applicable code sets permitted by the Implementation Guides for that purpose.

The NDC code set is maintained by the Food and Drug Administration (FDA) within HHS. It is required for use on the NCPDP claim format, which is the standard for retail pharmacy drug claims. Retail pharmacies have traditionally used the NDC. However, currently in the professional and institutional health care sectors, the NDC is used much less often. The primary code set used for reporting drugs and biologics in those sectors is the Healthcare Common Procedure Coding System (HCPCS)<sup>1</sup>. In the Transactions Rule, the Secretary adopted the NDC as the standard for reporting drugs and biologics on all claims. The Secretary adopted HCPCS codes as the standard for reporting supplies and orthotic and prosthetic devices and durable medical equipment, and, in combination with the Current Procedure Terminology, Fourth Edition, for reporting physician and numerous other health care services, on all claims.

HCPCS codes are grouped in “series.” Each series begins with an alpha character, and similar items are usually grouped under the same single or multiple series. The “J series” is comprised of drugs, primarily generic drugs, and traditionally these drugs have been limited to drugs that are payable under the Medicare program. Several drug codes, however, are present in other HCPCS series for reasons that are not relevant to this discussion. The NDC, on the other hand, is currently assigned to drugs subject to listing requirements under section 510 of the Federal Food, Drug, and Cosmetic Act. The NDC is assigned to generic as well as brand name drugs. HCPCS codes are five positions in length, whereas the NDC adopted by the Transactions Rule, was originally developed as a 10-digit

<sup>1</sup> When the name of the Health Care Financing Administration was changed to the Centers for Medicare & Medicaid Services in 2001, the name of this coding system was changed from the “Health Care Financing Administration Procedure Coding System” to the “Healthcare Common Procedure Coding System.”



identifier and, when used in computer systems, may yield an 11-digit number.

With the adoption of the NDC as the standard, the HCPCS codes would not be permitted to be used in a HIPAA-compliant transaction, because the NDC would be the adopted standard for reporting drugs and biologics.

There have been many discussions about the use of the NDC in professional and institutional claims since publication of the Transactions Rule. Many members of the professional and institutional sectors did not believe that the NDC should be used on their claims. The NCVHS held hearings and heard the testimony of members of the health care industry on this issue. Information provided in that testimony led us to develop the proposal to repeal the NDC as the standard for reporting drugs and biologics on all but retail pharmacy drug claims. In CMS-0003-P (67 FR 38044), we explained why the Secretary adopted the NDC and why the Secretary was proposing the repeal.

CMS-0003-P (67 FR 38044) also solicited comments on an alternative proposal to adopt an alternative standard—in place of the NDC, to be used to report drugs and biologics on non-retail pharmacy transactions. We proposed that the HCPCS code set be the alternative standard. Below we discuss comments on the proposal to repeal the NDC and the proposal to adopt an alternative standard for non-retail pharmacy transactions.

We received approximately 200 comments on this issue. The comments fell into three major categories: (1) Repeal the NDC as the standard medical data code set for professional, institutional, and dental claims and have no standard code set; (2) repeal the NDC, but adopt HCPCS as the standard code set; and (3) retain the NDC as the sole standard code set for claims from all sectors.

*Comment:* A number of commenters supported our proposal to repeal the NDC and adopt no standard in its place. These commenters, many of which were major health care industry organizations, indicated the following: (1) The current Implementation Guide usage of the NDC should remain constant and the Implementation Guide should define when the NDC would be used; (2) if no code set was selected, the Implementation Guides should not permit payers to require providers to use local code sets for drugs and biologics; (3) the cost of converting to the NDC was very high and would not justify the benefits, if any; and (4) not naming a standard would give the industry time to fully evaluate current

practices and identify preferred alternatives.

Conversely, the proposed repeal was not favored by some Medicaid State agencies, as they are required to use the NDC to report drugs and biologics to receive drug rebates.

*Response:* We agree that repealing the NDC and having no standard would be responsive to the needs of health plans and health care providers who want to evaluate further the use of NDC. The absence of a standard would permit the use of any codes as long as that use is supported by the Implementation Guide for the transaction. Repealing the NDC and having no standard would also address the concerns of many health care providers who cited the high cost and low benefit of conversion; they could continue to use HCPCS codes. Having no standard would allow many health care entities to continue their current coding practices, reducing the implementation burden, and would accommodate State agencies' requirement to report NDCs for drug rebate programs. Additionally, if there were no standard, the selection of the code set to be used would likely be specified by health plans via trading partner agreements, as long as the Implementation Guides permitted that selection.

*Comment:* The majority of commenters supported the repeal of the NDC and the adoption of HCPCS as the sole standard for reporting drugs and biologics on non-retail pharmacy transactions. Many of these commenters were institutional providers. They indicated that drug information, which is often not reported on institutional claims, is rarely used to compute payment because claims are usually paid under prospective payment systems. Since drugs are rarely reported on institutional claims, institutional health care providers would derive no benefit from the expensive transition from HCPCS codes to the NDC.

*Response:* Repealing NDC and adopting HCPCS as the standard would allay the concerns of some health care providers that more health plans might decide to implement the NDC at some point in the future. However, adopting HCPCS as the sole standard would not respond to the needs of health plans and health care providers where the specificity of the NDC is needed to compute payment or collect drug rebates.

*Comment:* Other commenters supported retaining the NDC as the standard for reporting drugs and biologics on non-retail pharmacy drug claims. Much of the support for retaining the NDC came on behalf of

State Medicaid agencies, which must use the NDC in order to receive drug rebates.

*Response:* As we have indicated, the NDC retains certain advantages over HCPCS, such as in the area of computing payments and collecting drug rebates. Additionally, the NDC enables health care providers and health plans to track effectively the utilization of drugs and access certain manufacturer information regarding the drugs. We also acknowledge that State Medicaid agencies have strongly encouraged retaining the NDC for reporting drugs and biologics on non-retail pharmacy drug claims. Retaining the NDC, therefore, as the standard would respond to the needs of health plans and health care providers who need specificity in computing payments and collecting drug rebates. It would also foster consistent drug coding for claims and among health care providers.

Simply retaining the NDC as the sole standard, however, would not adequately respond to the express concerns of those health care providers who commented that the cost of conversion to NDC would be high while the benefits would be low or non-existent. Moreover, the majority of commenters did not support keeping the NDC as the sole standard for reporting drugs and biologics for non-retail pharmacy sectors. We concluded that adopting either the NDC or the HCPCS would fail to address many of the concerns raised.

In our considerations, we recognized that both the NDC and HCPCS remain two of the most prevalent and useful code sets for reporting drugs and biologics in non-retail pharmacy transactions. The benefits of each code set complement the other's advantages very well.

We therefore decided, as we had proposed in CMS-0003-P, to repeal the adoption of the NDC for institutional and professional claims, while allowing the NDC to remain the standard medical data code set for reporting drugs and biologics for retail pharmacy claims. We believe that this decision best addresses the majority of comments received, in that for institutional and professional claims, the choice of code set will continue to be governed by trading partner agreements. However, we wish to stress that the intent of this decision is to give covered entities the full range of choices in determining which code set to use with respect to these claims, including the HCPCS and NDC codes that have been adopted as standards for other uses. Covered entities that use HCPCS should utilize the established process for requesting new codes, rather



than supplementing the code sets with locally developed codes.

The result of this repeal will be that there is no identified standard medical data code set in place for reporting drugs and biologics on non-retail pharmacy transactions. The absence of a code set would not preclude the use of NDC for reporting drugs and biologics by covered entities on standard transactions. Covered entities could continue to report drugs and biologics as they prefer and agree upon with their trading partners.

Comments from the different parts of the industry demonstrated that no one code set is able to meet the different needs now addressed by the NDC and HCPCS. Adopting no standard at this point will allow for innovation, and permit development of new coding systems that meet the full range of business needs. Comments also indicated that the costs for a hospital or other institution to comply with the NDC for reporting drugs and biologics on institutional claims could exceed its costs for adopting all other HIPAA transaction standards. For many health care providers, entire claim systems would need to be replaced, re-engineered, or both.

We also considered the concerns expressed by the NUBC regarding the use of the NDC on institutional claims, including hospital claims. NUBC has indicated that reporting specific drugs on institutional claims introduces a systems technology requirement that is inconsistent with inpatient claims submission and institutional provider reimbursement, which are typically based on a Diagnosis-Related Group or per diem payment methodology. The NUBC has also expressed its belief that the NDC coding system is more suited for inventory control and is not appropriate for institutional provider billing, and further that the NDC pertains to retail pharmacy claims only and should not be applicable to institutional claims.

We are also aware that retaining the NDC as the sole standard for institutional claims would pose significant operational issues on institutional pharmacies because of systems incompatibility among the pharmacies, inpatient medical records, and inpatient accounting systems. Physicians generally order drugs for patients through the hospital pharmacy department by name, unit, and dosage frequency. The pharmacy department however does not reference the NDC to initiate the charge transaction. Additionally, the NDC formats do not provide information related to actual dosages administered, or provide a

methodology for multiple billing increments. Attempts by the industry to develop a complete crosswalk from the current HCPCS codes to the NDC have been unsuccessful.

Another important factor in our decision, as we mentioned in CMS-0003-P, was the information we received from the Subcommittee on Standards and Security of the NCVHS as a result of the public hearings it held on February 1, 2001, regarding HIPAA implementation issues and the NDC. In addition to the problems we identified above, concerns expressed during that meeting included the burden of training additional ancillary staff to use the NDC and the potential for increases in medical errors when new system interfaces for drug dispensing systems are created.

The NCVHS in a February 22, 2001, letter to the Secretary recommended that the Secretary repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in standard transactions other than retail pharmacy transactions. It also suggested that HCPCS codes as well as the NDC continue to be used in the standard institutional and professional claim transactions. Moreover, the NCVHS explained that it believes that no drug coding system in existence today meets all the needs of the health care industry. A future coding system that could be used effectively and efficiently for drug inventory, pharmacy transactions, patient care, billing arenas, and ensuring patient safety would be the best answer to this problem, according to the NCVHS.

We note therefore that another significant advantage to repealing the adoption of the NDC for reporting drugs and biologics in non-retail pharmacy standard transactions and not adopting a replacement standard code set at this time is that the industry and HHS will have time to explore the development of a new drug coding system to meet current and future needs of this sector of the health care industry. We would note that the Implementation Guides for institutional and professional claim transactions currently recognize the use of only the NDC and HCPCS codes for drugs and biologics. See the discussion at section G.2 below. The developer of a new code set could request that it be included in the guides via the DSMO maintenance process.

Thus, based on comments received and our own review of the available code sets, we believe that our decision to repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in all non-retail pharmacy transactions is the best

and most appropriate decision at this time. Repealing the NDC as the standard medical code set for reporting drugs and biologics in non-retail pharmacy transactions also raises opportunities for the development of a more robust drug coding system that overcomes the deficiencies inherent in the NDC and HCPCS codes for reporting drugs and biologics on standard transactions. For example, because of the inadequacy of existing codes for drug products, and the need for harmonization of medical terminology, the FDA has been working with the National Library of Medicine and the Department of Veterans Affairs to develop improved drug codes.

In preparing this final rule, we consulted with the FDA and noted that the FDA is preparing two new regulations that relate to the use of the NDC number that will be proposed for public comment soon. Both proposed rules will propose changes related to coordinating the NDC with bar coding. It is expected that the proposed changes will make the NDC number more useful to those who choose to use the NDC.

#### 5. Retail Pharmacy Drug Claims

The Transactions Rule adopted the NCPDP transaction as the standard for retail pharmacy drug claims (§ 162.1102(a)), and the ASC X12N 837—Professional Health Care Claim as the standard for professional services (§ 162.1102(c)). Neither of our May 31, 2002, proposed rules solicited comments on the formats to be used by retail pharmacies when submitting claims for drugs, supplies, durable medical equipment, prosthetics, orthotics, and professional services.

The DSMOs are currently discussing this item in their consideration of two pending change requests that were introduced into the DSMO process within the past year. (These requests were not submitted in time to be considered under the “fast track” approach described in this final rule in section I. C., “Designated Standard Maintenance Organization (DSMO) Process.”)

In submitting comments on issues presented in our two May 31, 2002, proposed rules, some commenters included comments on the formats for retail pharmacy drug claims for items and services other than drugs. Such items included syringes, which are supplies that are usually purchased with drugs such as insulin. Services included consultations with patients and the administration of vaccines (such as the influenza vaccine) to individuals. The issue of the format on which retail pharmacy supply claims should be billed is tied closely to business

practices of retail pharmacies and the administration of pharmacy and medical benefits by health plans. The Transactions Rule adopted a standard for retail pharmacy drug claims, and adopted standards for professional, institutional, and dental claims. It did not state specifically, except with respect to retail pharmacies using the NCPDP claim format, the particular types of health care providers that would use the professional and institutional ASC X12N 837 standard claim formats. The Implementation Guides themselves do not specify the types of health care providers that are expected to use those standards.

Commenters requested additional clarification of the formats (the implementation specifications) to be used by retail pharmacies in submitting claims for supplies and professional services. Below are specific comments and our responses.

*Comment:* We received comments requesting that the Secretary adopt the NCPDP format for retail pharmacy supplies and services. We also received some comments requesting that the Secretary adopt both the NCPDP format and the ASC X12N 837 format for submitting claims for supplies and services furnished by retail pharmacies, and allow the type of benefit (pharmacy or medical) to determine which format would be used. Commenters stated that splitting claims by billing drugs using the NCPDP format and supplies using the ASC X12N 837 Professional format was burdensome, and that the real-time functionality achieved with the NCPDP format could not be used for billing the supplies that are furnished in conjunction with dispensing the drug. We received conflicting comments regarding the billing of professional pharmacy services using the NCPDP format. These commenters preferred using the ASC X12N 837 Professional claim for billing professional pharmacy services.

*Response:* The commenters expressed differing business needs and concerns. Some commenters included supporting rationale and justifications, while others did not. It is apparent that much information still needs to be obtained and analyzed before we consider modifying the standards published in the Transactions Rule. We are aware that the comments do not represent a complete picture of the industry because we did not solicit comments specifically on this issue. Since formats for billing retail pharmacy supplies and professional services were not proposed in CMS-0005-P (67 FR 38050), or CMS-0003-P (67 FR 38044), many people who

may have information pertinent to this issue did not comment on it.

*Comment:* Approximately one-third of the commenters stated that the NCPDP format should not be used by retail pharmacies to submit claims for professional services; they did not provide supporting rationale.

*Response:* The NCPDP format is not used extensively by retail pharmacies to bill for professional services. Many retail pharmacies currently use the CMS-1500 "Health Insurance Claim" (the professional paper claim) in submitting claims for professional services.

*Comment:* Some commenters indicated that a more consistent and effective approach would be for retail pharmacies to use the NCPDP format for all claims, regardless of the type of service. Some commenters also elaborated on the benefits of NCPDP's real-time transaction.

*Response:* This approach would benefit retail pharmacies, which currently use the NCPDP format. However, the Transactions Rule states that claims for drugs are to use the NCPDP claims transaction. This means that retail pharmacy claims that are not for drugs are to use the ASC X12N 837 Professional claims transaction.

*Comment:* Other commenters believed that both the NCPDP and the ASC X12N formats should be used by retail pharmacies. Some of these commenters stated that drug claims and claims for supplies that are closely related should continue to be billed on the NCPDP format, and that claims for professional services and supplies that are not tied to drugs should be billed on the ASC X12N 837 Professional, which is the adopted standard for claims for supplies and professional services, and is the transaction standard that other health care providers will use for these types of claims. Several of these commenters indicated that the NCPDP format should be used for claims that fall under pharmacy benefits, and the ASC X12N 837 Professional format should be used for claims that fall under medical benefits. Some commenters expressed concern about the lack of clear industry guidelines for determining pharmacy benefits and medical benefits. Others stated that both formats should be adopted, and that health plans should determine the situations for the use of each.

*Response:* The Transactions Rule adopts in § 162.1102(a) the NCPDP format for retail pharmacy drug claims and the ASC X12N 837 Professional claim format for claims for supplies and professional services. The Transactions Rule does not specify the items or

services that would be billed on the ASC X12N 837 Professional claim. We will be providing additional guidance by other means on this issue.

#### *C. Proposal to Adopt Modifications to the Standards Adopted in the Transactions Rule*

We proposed in CMS-0005-P (67 FR 38050) to adopt modifications to certain standards adopted in the Transactions Rule (65 FR 50312). The modifications we proposed were the result of the DSMO process to maintain standards adopted by the Secretary and to process requests for adopting new standards or modifying adopted standards. (The DSMO process is described in section I. C. of this rule.)

The versions of the Addenda adopted in this final rule are referenced by the suffix "A1" and dated October 2002. It is important to note that these versions become final with publication of this final rule. Consequently, the October 2001 date is revised to October 2002 to reflect the final versions of the adopted Addenda.

#### *D. Composition of the Addenda*

Addenda are defined as modifications to items in the implementation specifications that could be considered impediments to implementation. They are first published in draft form and go through the rulemaking process before becoming final.

Two hundred thirty-one change requests were submitted to the DSMOs for consideration. Eighty-five were returned to submitters because the Implementation Guides already met the specific business need, or the need was not well substantiated; 21 were determined to be unnecessary for initial implementation and were, therefore, recommended for future changes; six were withdrawn by their submitters; and seven were referred to the Secretary as policy issues requiring resolution. The remaining 115 change requests were approved by the DSMOs and comprise the various Addenda.

Forty-eight of the 115 change requests were maintenance items to correct minor errors, or provide clarifications in the standards. Maintenance changes are technical corrections made by DSMOs to correct typographical errors or other non-substantive changes. Maintenance changes exclude activities related to the adoption of a new standard or implementation specification or modification to an adopted standard or implementation specification. Maintenance changes are typically changes that are obvious to readers of the Implementation Guides, are not controversial, and are essential to

implementation. These maintenance items are the result of DSMO change requests that were approved and recommended for adoption via the DSMO process. Therefore, we are not including a discussion of them in this final rule.

The remaining 67 of the 115 change requests were for substantive modifications to the standards, and they are detailed below.

#### *E. Proposed Modifications to the Standards*

- Changing usage of data elements from required to situational (about 20 percent of total requested changes).

Required usage of data elements means that particular data elements must be used every time the transaction is conducted. Situational usage of data elements means that, when certain specified situations or conditions exist, particular data elements must be used when the transaction is conducted. Those who submitted DSMO change requests pointed out several data elements for which the adopted standards required usage in all cases, but that was only needed in certain situations. Usage of these data elements was made situational in the Addenda, with the situations explicitly defined. Examples follow:

1. Many health plans store Healthcare Provider Taxonomy Codes when health care providers enroll in the health plan, so there is no need to send this information on every claim. Healthcare Provider Taxonomy Codes are data elements that identify the type, classification, and specialization of providers furnishing health care. The NUCC maintains these codes. The Washington Publishing Company makes the Healthcare Provider Taxonomy Codes available on its Web site (<http://www.wpc-edi.com>). The Healthcare Provider Taxonomy Codes now will be reported only when claim adjudication is known to be impacted by the presence of the code.

2. In another case, "date last seen by physician" (used for certain physical therapy claims) is needed only by Medicare, so usage was changed from required on all claims, to required "when known to impact the payer's adjudication process."

- *Removal of certain data elements* (about 20 percent of changes).

Several data elements were removed because they do not appear to be needed by any covered entity.

- *Allowing certain information to be reported via external code sets rather than via data elements defined in the transaction* (about 20 percent of changes).

ZIP codes, maintained by the U.S. Postal Service, are an example of an external code set. Revisions and updates for transaction data elements adopted by the Transactions Rule must go through the DSMO change request process, while revisions to external code sets require requesters to submit requests to the organizations that maintain the code sets and are not subject to the DSMO review process.

There were several instances where external code sets could be used to indicate certain data elements. The replacement of data elements with external code sets will allow the maintainers of those external code sets to update the codes more easily, as opposed to having the DSMOs make changes to the standards themselves. Two external code sets adopted by the Addenda are special program indicator codes and newborn birth weights.

- *Adding additional functionality to some transactions* (about 40 percent of changes).

Requesters suggested several additional data elements, codes, or loops to enable them to perform certain business functions in the transactions.

These included cross-referencing two subscriber IDs (surviving spouse and dependents) and sending a patient's primary care physician number.

#### *F. Comments on the Modifications Included in the Addenda*

CMS-0005-P (67 FR 38050) established the scope for technical comments by limiting comments to only those items being added or changed by the Addenda.

Numerous recommendations and suggestions submitted in the comments, which were not considered critical for implementation, will be considered for improvements or clarifications to future versions of the implementation specifications.

Because the comments were technical in nature, relating to specific data elements and segments, and applied to implementation specifications that were developed and are maintained by external organizations, such as the ASC X12N and the NCPDP, the Secretary could not address all of them directly. Therefore, we analyzed the public comments received to determine which comments fell in this technical category. We consulted with representatives from each of the DSMOs on these technical comments. Some of the technical comments were referred to the external organizations that develop the standards, such as the ASC X12N transaction workgroups, for additional review and consultation.

Comments that did not pertain specifically to the proposed Addenda were considered and determined to be more appropriately addressed through the DSMO Change Request process.

The majority of comments we received generally supported adoption of the proposed Addenda. Most commenters agreed that adopting these proposed changes is necessary to permit successful initial implementation of the standards within the industry. The Workgroup for Electronic Data Interchange (WEDI), the American Hospital Association (AHA), the National Uniform Claim Committee (NUCC), a number of Medicaid State agencies, the Health Insurance Association of America (HIAA), the Blue Cross Blue Shield Association (BCBSA), and the American Medical Association (AMA) were among the numerous health care providers, health plans, and professional organizations that submitted comments expressing support for adoption of the proposed Addenda. Some commenters suggested that work on the implementation specifications continue in order to improve the clarity relating to specific situational data elements and to ensure clear, consistent interpretations and implementation by health plans.

Commenters unanimously supported many specific Addenda items, for example:

- The proposal to use existing UB-92 Condition Codes for reporting special program indicators, as well as UB-92 Value Codes to report newborn birth weights. These changes would eliminate differences in the way this information is handled for electronic and paper submission of claims. It is important wherever possible to follow the same data development paths for both paper and electronic submission in order to simplify the capturing and reporting of billing information.

- The deletion of unneeded data segments and the clarification of ambiguous usage notes.

We discuss other comments on specific modifications below. They are organized according to specific adopted transaction standards.

The Addenda are not stand-alone documents. They are supplemental implementation specifications to the initial standards adopted in the Transactions Rule. In this final rule, we therefore adopt the Addenda as part of the standards to which they apply.

#### *G. Transaction Standard for Health Care Claims or Equivalent Encounter Information*

In CMS-0005-P (67 FR 38050), we proposed to adopt the following:

- Addenda to Health Care Claim: Dental, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X097A1.

- Addenda to Health Care Claim: Professional, Volumes 1 and 2, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X098A1.

- Addenda to Health Care Claim: Institutional, Volumes 1 and 2, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as the standard for health care claims or equivalent encounter information.

#### 1. Transaction Standard for Health Care Claims or Equivalent Encounter

Information: Institutional

*Comment:* A number of commenters objected to the usage note in the Addenda that requires reporting of HCPCS codes for all outpatient claims, because some outpatient services do not have HCPCS codes established for them. Commonly used revenue codes submitted without HCPCS codes are 250 (pharmacy drugs), 270 (medical supplies), 370 (anesthesia supplies), 710 (recovery room), and 762 (observation). HCPCS codes do not exist for many of these services. The commenters noted that the use of unlisted (miscellaneous) HCPCS codes in situations where a specific HCPCS code does not exist to describe the service or supply could result in the rejection of an entire claim because additional documentation is required for defining the unlisted code. An increase in the use of unlisted codes for these situations would cause significant claim processing delays and rework. Even though there is no additional line-item payment for these revenue codes, they must be submitted because Ambulatory Patient Classification (APC) reimbursement values are calculated by looking at all of the services submitted.

*Response:* We agree with these commenters that the Addenda proposal to require the use of HCPCS codes on all outpatient claims did not account for those services that do not have assigned HCPCS codes. The usage note was modified by the ASC X12N to indicate that HCPCS codes are only required to be reported for services when a HCPCS code exists for that particular service.

*Comment:* Several commenters objected to the Addenda's removal of the requirement for diagnosis information on "Hospital Other" bill types. "Other" is defined by the NUBC as diagnostic services, or home health services not under a plan of treatment. For example, a family physician may send blood work to a hospital-based

laboratory. The hospital never sees the patient. Some health plans use this diagnosis information to pay or reject claims based on whether a service is medically necessary, experimental, or cosmetic. The adopted Addenda modify the requirement for this diagnosis information by making its use situational, with a note explaining that a diagnosis is not needed for "Religious Non-Medical" claims and "Hospital Other" bill types.

*Response:* The original transaction standards required this diagnosis information on all inpatient and outpatient claims. The DSMO change request for not requiring the diagnosis information on certain types of claims was strongly supported by the industry because principal diagnosis information is not needed for certain hospital bill types. For example, when a physician sends a patient's blood work to a hospital-based laboratory, the hospital will bill for those services using the "Hospital Other" bill type. The hospital never sees the patient and would have no record of the patient's principal diagnosis information. We support the Addenda change to delete the requirement for principal diagnosis information in all situations, since in many cases obtaining this information creates an administrative burden when it is not readily available and not used.

*Comment:* We received numerous comments on the Addenda's institutional claim usage of Healthcare Provider Taxonomy Codes, which identify the specialty of a health care provider that provided medical services. In the implementation specification adopted in the Transactions Rule, Healthcare Provider Taxonomy Code information usage was required at the line level and the claim level for institutional claims. The Addenda modify the required use of the Healthcare Provider Taxonomy Code information at the line level and the claim level for institutional claims by making its use situational. The situation that would require its use is if the information is known to impact claim adjudication. Commenters stated that hospitals often have many caregivers involved in the delivery of a particular service, and that it is impractical or impossible in many instances to report a single Healthcare Provider Taxonomy Code or other associated provider identification at the line level. To require such reporting would impose a tremendous burden on hospitals to implement massive new system changes to track which caregivers were responsible for providing each individual service and to incur costs that would never be recouped through

payment differentials payers would assign to the service. Commenters suggested that HHS follow the NUBC recommendation to delete all references to the use of Healthcare Provider Taxonomy Codes from the institutional claim Implementation Guides. However, other commenters cited examples and reasons why Medicaid State agencies require the taxonomy information, including determining appropriate reimbursement, editing and auditing claims, routing data for State and Federal reporting, and detecting fraud and abuse. Use of taxonomy information on the institutional claim would allow Medicaid programs to use the most up-to-date information available for claim pricing and payment methodology reports. These commenters indicated that removing taxonomy codes from institutional claims could impact health care provider reimbursement and would involve complex policy changes for Medicaid State agencies.

*Response:* After extensive deliberation on this issue and evaluation of current business practices among institutional health care providers, ASC X12N has removed the required usage of Healthcare Provider Taxonomy Codes from most segments in the ASC X12N 837 Institutional Implementation Guide. We attempted to find specific situations in the industry documenting the need for this particular Healthcare Provider Taxonomy Code use. Only one health plan identified a specific need for this information at the Billing/Pay To Provider level for the institutional claim. Usage at this level will remain situational to accommodate those business situations when Healthcare Provider Taxonomy Code information is needed.

*Comment:* Numerous commenters requested that the requirement to report physician name and ID number at the line level be eliminated. The implementation specifications adopted by the Transactions Rule established this requirement. The Addenda changes recommended by the DSMOs modify the required usage to situational. The situation that would require its use is if the information is known to impact claim adjudication. According to current billing practices, an institutional claim form summarizes services and supplies provided by a hospital facility. The attending physician who has ultimate responsibility for coordinating hospital services is reported at the claim level. Line level reporting of each health care provider would be redundant since individual professional services are separately billed according to professional billing guidelines.

*Response:* After considerable discussion and evaluation of current industry practices, we determined that this information is available, but not currently required, on institutional claims. The implementation specifications adopted by the Transactions Rule established the usage of line level provider information as required when the provider information at the line level was different from that at the claim level. The Addenda for the implementation specifications modify the usage of line level provider information from required to situational. The specific situation when this information would be required is when line level provider information is known to impact claim adjudication.

*Comment:* A few commenters noted that a usage change instruction for Operating Physician Specialty Information points to an incorrect segment.

*Response:* We agree with this comment. ASC X12N has made the appropriate corrections and added this modification to the Addenda adopted by this final rule.

## 2. Transaction Standard for Health Care Claims or Equivalent Encounter Information: Professional

*Comment:* Several commenters stated that the implementation specification requirement proposed for the use of the NDC conflicted with the proposed regulation text for CMS-0003-P (67 FR 38044). In our CMS-0003-P proposed rule, we proposed repealing the NDC for reporting drugs and biologics on non-retail pharmacy transactions and that no standard for reporting drugs and biologics on non-retail pharmacy transactions be adopted at this time. CMS-0005-P (67 FR 38050) proposed adoption of the Addenda that required usage of the NDC information when necessary to add definition to a particular product. One commenter suggested that this be clarified by adding a mutually defined "ZZ" qualifier to permit usage of any code sets based on trading partner agreements.

*Response:* This final rule adopts the modified Addenda approved by ASC X12N in October 2002. The Addenda permit use of either the NDC or HCPCS to code drugs and biologics on non-retail pharmacy claims, but (with limited exceptions) do not permit other codes to be used for this purpose. However, this choice of either HCPCS or NDC codes is not consistent with our decision, reflected in § 162.1002(c) below, to repeal the standard code set for drugs and biologics for non-retail pharmacy transactions and to permit the use of all code sets in order to encourage development of a single code set that

will meet the needs of the entire health care industry. We expect that the choice of either the HCPCS or the NDC codes afforded by the Addenda will, in the usual case, result in covered entities in the non-retail pharmacy sectors of the industry continuing to code drugs and biologics as they do now, whether by NDC or by HCPCS. The Addenda will thus not create a disincentive for industry to develop, and migrate to, a single code set for use by the industry.

Although we agree that in this respect the Addenda are not consistent with our underlying policy choice regarding the code sets for drugs and biologics for non-retail pharmacy transactions, the adopted Addenda contain many important changes to the Implementation Guides that are essential if industry is to be able to test and implement the transactions in question smoothly and on time. Because we cannot, under the statute, choose among provisions in an industry-adopted standard guide without going through negotiated rule making, the critical need for the remainder of the changes in the Addenda has led us to adopt the Addenda in their present form. We intend, however, to work with industry to align the Addenda with the policy reflected at § 162.1002(c) and adopt a further modification of the standards to effect this alignment in the next update. Should we not be able to reach agreement on the inconsistency between our policy decision and the policy reflected in the Implementation Guides, we intend to pursue our options under the statute that include negotiated rule making. We recognize that the existence of what is, in effect, two standards for coding drugs and biologics within the transactions in question may cause problems between health plans and health care providers and may in some cases result in noncompliance. It is unlikely that we would pursue any such instances of noncompliance, in light of the competing demands for enforcement resources and the inconsistency between our policy decision and the policy reflected in the Implementation Guide.

With respect to the comment about ZZ codes, the adopted Addenda only permit use of ZZ qualifiers for certain situations. Thus, the problem discussed above likewise exists with respect to such codes, and we adopt the same approach thereto.

*Comment:* One commenter listed three modifications that had been approved by the DSMOs but were not included in the Addenda specifications. These modifications related to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for Dialysis Patients.

*Response:* We verified that these modifications were adopted in the proposed Addenda but due to typographical errors were inadvertently not included in the proposed Addenda. ASC X12N has corrected these errors and added these modifications to the Addenda adopted by this final rule.

*Comment:* We received many comments from anesthesiology providers requesting that we not adopt the proposed usage instruction that allows reporting anesthesia services in minutes only. Current business practices require that reimbursement for anesthesia services be based on total anesthesia time in minutes or units. Adopting this proposed usage instruction in the Addenda would impact reimbursement methodologies and payment amounts for anesthesia providers.

A number of commenters requested HHS to adopt a standard definition for anesthesia time. A generally accepted definition for most payers, including Medicare, that is consistent with the American Society of Anesthesiologists' definition, defines anesthesia time as starting when the practitioner begins to prepare the patient for anesthesia services and ending when anesthesia services are no longer being provided and the patient is safely in postoperative care. However, a minority of payers account for anesthesia time differently, requiring multiple reporting for face-to-face start and stop times, if there are different clinical activities in a particular service. A commenter pointed out that the sporadic need to depart from a widely accepted methodology is burdensome and results in frequent reporting errors.

*Response:* We agree with the comment to delete the usage instruction requiring the reporting of minutes only for anesthesia services. Based upon various payment systems for anesthesia services that depend upon reporting unit information on claims, and the various methods for calculating one unit of time, we determined that adopting a standard requiring that only minutes be reported would impact anesthesia providers' ability to report their services adequately. Regarding the request for a standard definition for anesthesia time, we believe that the applicable comments actually seek further clarification of health plans' reimbursement policies, which are not the subject of these transaction standards.

*Comment:* Several commenters objected to a modification of the requirement for spinal and non-spinal manipulation service information. This

information was previously required on all spinal manipulation claims. The Addenda limit this requirement to Medicare Part B chiropractic claims. For some health plans, this information applies to contractual benefit exclusions and is used to adjudicate claims. Since osteopathic manipulation procedure codes can represent either spinal or non-spinal manipulations, the spinal manipulation service information segment is used by some health plans to distinguish between spinal and non-spinal services.

*Response:* We agree with this comment. ASC X12N has added a usage note to the Addenda adopted by this final rule to require the spinal manipulation service information segment when needed for claim adjudication.

*Comment:* Numerous commenters supported the Addenda modification that changed the usage for Healthcare Provider Taxonomy Codes from required to situational. However, one commenter suggested that usage of Healthcare Provider Taxonomy Codes be completely removed from the Professional claim Implementation Guide.

*Response:* Commenters generally supported the Addenda modification for usage of the Healthcare Provider Taxonomy Codes from required to situational. After extensive review and discussion of this topic, we adopt the proposed Addenda's situational usage of Healthcare Provider Taxonomy Codes on the Professional claim.

*Comment:* We received comments indicating that "Date Last Seen" information was required by a number of payers. The Addenda specified that only Medicare required this information.

*Response:* We have confirmed that other health plans do need these data. The Secretary adopts the ASC X12N modification for situational usage of this date information when it impacts the health plan's claim adjudication process.

*Comment:* One commenter requested that a description for the acronym "EPSDT" be added to the Implementation Guide.

*Response:* We believe that this information will clarify Implementation Guide requirements. Accordingly, the acronym for Early and Periodic Screening for Diagnosis and Treatment ("EPSDT") and its definition will be adopted. ASC X12N revised the Addenda to include this clarification.

*Comment:* A number of commenters referenced variations in the use of "performing provider" and "rendering

provider" information, and questioned the different terminology.

*Response:* In the Addenda performing provider (PE) and rendering provider (PR) are separate and distinct data elements. "PE" and "PR" have the same business meaning of identifying the provider who furnishes a service. However, these data are named differently because they are referenced in separate sections of the Implementation Guide. "PE" is used to denote the Performing Provider in the PRVO1 section. "PR" denotes the Rendering Provider at the Loop 2310 B segment.

### 3. Transaction Standard for Health Care Claims or Equivalent Encounter Information: Dental

*Comment:* We received a number of comments requesting the use of HCPCS modifier codes for dental claims. The commenters stated that using HCPCS modifier codes improves the efficiency of processing electronic dental claims by providing necessary detail and allowing more accurate dental claim adjudication. Other commenters opposed the use of HCPCS modifier codes with the adopted Code on Dental Procedures and Nomenclature standard, stating that most dental billing systems do not support procedure code modifiers. Those commenters pointed out that the use of HCPCS modifier codes is likely to increase paper claims and would perpetuate the current lack of code standardization for payment purposes and undermine the goal of administrative simplification.

*Response:* The Code on Dental Procedures and Nomenclature (The Code), as maintained and distributed by the American Dental Association (ADA), is the adopted standard code set for reporting dental services. Using HCPCS modifier codes for dental claims reporting would require the adoption of an entire additional code set for standard dental transactions, when only 20 to 30 modifiers are needed. We recognize that no single code set in use today meets all of the business requirements related to the full range of health care services and conditions that exist, and that adopting multiple standards may be a way to address code set inadequacies. Rather than adopt the HCPCS modifier codes in addition to The Code for dental transactions, we suggest working with The Code maintainers, the ADA, to develop and add modifiers that will meet the needs of the dental industry. Dental professionals and the public may submit requests at <http://www.ada.org/prof/prac/manage/benefits/cdtform.html>.

*Comment:* We received one comment suggesting that the phrase "for services provided or proposed" be added after Dental Health Care Claims (§ 162.1102(b)). The ASC X12N 837 dental claim transaction was designed and is used to submit a request for pre-determination and pre-authorization of dental benefits. Since this function was not identified in the Transactions Rule or in the Addenda, the submission of an electronic inquiry for determining payment for proposed dental services is not an adopted transaction standard. This commenter also suggested that the word "Dental" be deleted from § 162.1302(b), Standard for Referral Certification and Authorization, dental, professional, and institutional referral certification and authorization 004010X094A1 because the adopted implementation specification for ASC X12N 278 states that it is not intended for dental pre-determination pricing, and that instead the ASC X12N 837 Dental transaction should be used for this purpose. The commenter also stated that there is no existing or anticipated need for referral certification and authorization using the ASC X12N 278 for dental services. Dental systems support the ASC X12N 837 Dental for pre-approval of dental benefits. We received conflicting comments from Medicaid-identified commenters who expressed a need for using the ASC X12N 278 for dental referral certification and authorization, and that indicated that all dental systems do not completely support the ASC X12N 837 Dental for pre-approval of dental benefits.

*Response:* We have determined that the ASC X12N 837 Dental claim is commonly used by the dental industry for pre-determination and pricing of dental services. This function does not meet the definition for the Referral Certification and Authorization Transaction in the Transactions Rule at § 162.1301, and is not a transaction standard adopted by the Transaction Rule, or proposed in CMS-0005-P.

Although not a HIPAA standard, pre-determination and pricing functionality are available for use with the ASC X12N Dental claim. However, ASC X12N has not adopted a standard response transaction for use with this function. ASC X12N will be developing and modeling the business use of the pre-determination and pricing transaction in coordination with the DSMOs for future consideration as a transaction standard and the subject of a later rule.

Based upon comments received, we also have determined that there is an expressed business need for use of the ASC X12N 278 for dental referral

certification and authorization. The word “dental” will remain in § 162.1302 so that use of ASC X12N 278 is available for referral certification and authorization of dental transactions.

In summary, adding the phrase “for Services Provided or Proposed” to § 162.1102(b) will not be adopted at this time. However, this does not preclude use of the ASC X12N 837 Dental claim pre-determination and pricing functionality. The ASC X12N 278 will remain available for dental use of the Referral Certification and Authorization Transaction. The dental industry will have available use of the ASC X12N 278 adopted transaction standard for referral certification and authorization transactions and the ASC X12N 837 Dental claim for pre-determination and pricing activities for which no standard has been adopted.

*Comment:* A number of commenters disagreed with the Addenda modification that added “Assistant Surgeon” and “Rendering Provider” information to both the line level and the claim level for dental claims. Commenters stated that tracking and reporting this information would be an enormous burden for health care providers and not conducive to administrative simplification.

*Response:* In order to reduce the administrative burden on health care providers and prevent the potential confusion that could result from sending or receiving a claim with both a “Rendering Provider” and an “Assistant Surgeon” at the same level, ASC X12N has added a note to the Addenda instructing the user not to report the “Assistant Surgeon” information when the “Rendering Provider” information is reported at the line level of the claim.

*Comment:* We received a few comments supporting the Addenda modification that changed the usage from required to situational for Healthcare Provider Taxonomy Codes.

*Response:* The Addenda modified the use of the Healthcare Provider Taxonomy Codes from required to situational on the dental claim.

*Comment:* One commenter indicated support for the Addenda and specifically supported the addition of a new code set value in the Addenda, “service provider number,” which the commenter maintained was a necessary data element for managed care programs.

*Response:* This comment supports one of the Addenda modifications adopted by this final rule that was required to permit initial implementation of the standards. Adding the “service provider number”

code set value is an example of a technical addition that better defines the implementation specifications.

#### *H. Transaction Standard for Eligibility for a Health Plan*

We proposed adoption of the Addenda to Health Care Eligibility Benefit Inquiry and Response, ASC X12N 270/271, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 as the standard for the dental, professional, and institutional health care eligibility benefit inquiry and response transaction.

*Comment:* We received two comments that expressed support for adoption of the Addenda to the ASC X12N 270/271 transaction.

*Response:* No additional comments or specific detailed requests were received for these Addenda.

#### *I. Transaction Standard for Referral Certification and Authorization*

We proposed adoption of the Addenda to the Health Care Services Review—Request for Review and Response, ASC X12N 278, Version 4010, October 2002, Washington Publishing Company, 004010X094A1 for the dental, professional, and institutional referral certification and authorization transaction.

*Comment:* We received a number of comments about use of the Logical Observation Identifier Names and Codes (LOINC™). The comments stated that use of this code set was confusing and requested that the usage requirement be deleted or a clarifying note be added. The Addenda state that this code set is not allowed for use under HIPAA at this time. It is unclear why this code set would be included in the Addenda if the code set is not an adopted standard code set.

*Response:* The LOINC™ code set was intended by the SSOs to increase functionality of the transaction. It has not been adopted as a national standard code set, but can be used in implementing this transaction. The Addenda add the use of the LOINC™ code set as an EDI option for responding to requests for additional information when conducting the standard Referral Certification and Authorization Transaction.

*Comment:* We received a number of comments suggesting that the Addenda usage notes that allow attachment of electronic documentation to this transaction were confusing because they appeared to conflict with the Claims Attachment Transaction, mandated by HIPAA but not adopted by the Secretary at this time.

*Response:* The Claims Attachment Transaction standard mandated by HIPAA, but not adopted by the Secretary, is available for voluntary EDI use from the Washington Publishing Company at the following Web site: [www.wpc-edi.com](http://www.wpc-edi.com). The functionality of this transaction allows the electronic transmission of documentation associated with a claim. It can also function as a response for the Referral Certification and Authorization Transaction, when additional information is requested. The use of the electronic attachment with the Referral Certification and Authorization Transaction is considered a two-way transaction: an EDI request and its associated EDI response. Use with the claim transaction can be either a one-way (required attachment is sent with the claim and not as a response to a request), or a two-way transaction. The Addenda do not require the provider to respond to this request for additional information by using the Claims Attachment Transaction. However, if the provider wants to respond using an EDI transaction, the preferred method is the Claims Attachment Transaction.

We agree that further clarification on the circumstances when these two transactions may be used is needed. ASC X12N has modified the standard for the referral certification and authorization implementation specification to illustrate the model use of these transactions for other applications.

*Comment:* We received one comment that referenced the absence of a needed segment regarding Dependent Detail information. The Dependent Detail loop ID 2010DA for Dependent name 270 DTP date or time period is not referenced in the Addenda. This segment is needed to convey subscriber dependent information when the dependent is the patient.

*Response:* We agree that this is an error. ASC X12N has corrected it in the adopted Addenda.

*Comment:* There were approximately 20 highly technical comments relating to requests for clarification, missing elements, misspelling, minor revisions, and improvements to the Implementation Guides.

*Response:* Because of their technical complexity, these comments that involved modifications to specific loops and data elements in the implementation specifications were referred to the ASC X12N Workgroup. The following is a summary of these comments:

- Four commenters requested minor revisions, which included creating a response code to tell the provider that



additional medical information is needed, correcting a typographical error for repeating a data element, adding a qualifier to enable the provider to link a request with an attachment, and defining two segments that only support paper attachments. These requests have been reflected in the revised Addenda.

- Fourteen of the commenters asked for additional clarification on the appropriate use of the standard for referral certification and authorization as a two-way transaction. The Implementation Guide is modified to illustrate the model use of this transaction to include a follow-up EDI or non-EDI response.

- One commenter asked a question relating to whether a transaction should be rejected if there is no patient event tracking number (TRN) segment for the patient, when the patient is not the subscriber. ASC X12N clarified in the Addenda that the transaction should not be rejected. The TRN usage instruction was made specific about when the data are required.

- One of the commenters requested that a new code be developed to replace the Assigned By Receiver (ABR) code rather than use an existing code to define an element for which it was not intended. A data maintenance request has been approved to have a code added, but it will not be in effect for the ASC X12N 4010 Version of the Implementation Guide.

#### *J. Transaction Standard for Health Care Claim Status*

We proposed the adoption of the Addenda to Health Care Claim Status Request and Response, ASC X12N 276/277, Version 4010, October 2002, Washington Publishing Company, 004010X093A1 as the standard for the health care claim status transaction.

We did not receive significant comments on this proposal.

#### *K. Transaction Standard for Enrollment and Disenrollment in a Health Plan*

We proposed the adoption of the Addenda to Benefit Enrollment and Maintenance, ASC X12N 834 Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1 as the standard for enrollment and disenrollment in a health plan transaction.

We did not receive significant comments on this proposal.

#### *L. Transaction Standard for Health Care Claim Payment/Advice*

We proposed the adoption of the Addenda to Health Care Claim Payment/Advice, ASC X12N 835,

Version 4010, October 2002, Washington Publishing Company, 004010X091A1 as the standard for dental, professional, institutional, and pharmacy health care payment and remittance advice transactions.

We did not receive significant comments on this proposal.

#### *M. Transaction Standard for Health Care Premium Payments*

*Comment:* A number of commenters pointed out that adoption of the ASC X12N 004010X061 and ASC X12N 004010X061A1 standards were not included in CMS-0005-P.

*Response:* We received comments pointing out that the transaction standard for Health Care Premium Payments, the ASC X12N 820, 004010X061 and Addenda, 004010X061A1, were omitted from CMS-0005-P. We did not specifically intend to exclude this transaction standard and its Addenda from the proposed rule. The modification for the Addenda to this Implementation Guide provides the same guidance as the Addenda for the other transaction standards; the modification provides guidance to the industry, in section A.1.3.1.2, in handling decimal points in monetary transactions. Nevertheless, we recognize that these Implementation Guide modifications were not expressly identified and separately listed in CMS-0005-P, and thus we are including them as follows in section IV below.

#### **IV. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice and public comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We find for good cause that it is unnecessary to undertake notice and comment rulemaking procedures for this final rule because the Addenda modifications for § 162.1702 "Standard for health care premium payments," § 162.1802 "Standards for coordination of benefits," and technical modifications approved by the DSMOs (relating to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for

Dialysis Patients) offer no substantive changes to the standard and Addenda and merely provide explanatory guidance.

The Addenda for the Health Plan Premium Payments Transaction provides the same guidance to the industry as the Addenda for other adopted transactions that were proposed in the proposed rule at 67 FR 38050.

The Coordination of Benefits Transaction Standard is a variation of the health care claim transaction for institutional, dental, and professional providers that was proposed in CMS-0005-P.

The three modifications approved by the DSMOs but not included in the Addenda specifications are merely technical corrections relating to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for Dialysis Patients for a single transaction standard. These corrections in essence correct a typographical error in the draft Addenda and do not require any data elements to be changed.

We received comments on the standard for the health care claim, and have responded to those in this final rule. Because each of the transaction standards adopted by the Transactions final rule has Addenda that were approved for use by the industry, we are adopting the Addenda for each of the proposed transactions so that implementation of the Addenda for each of the adopted standards will be consistent. Therefore, for good cause, we waive notice and public comment procedures under 5 U.S.C. 553(b)(B).

#### **V. Collection of Information Requirements**

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.



Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The information collection requirements and associated burdens in §§ 162.1002, 162.1102, 162.1202, 162.1302, 162.1402, 162.1502, 162.1602, 162.1702, and 162.1802 are subject to the PRA. The burden of these standards is addressed under OMB approval number 0938-0866.

We are submitting a copy of these revisions to the regulation sections to OMB for its review of the information collection requirements. We will also submit the all of the revisions for review and reapproval under 0938-0866. These revisions are not effective until OMB has approved them. If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Office of Strategic Operations and Regulatory Affairs, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, MD 21244, Attn: Julie Brown, CMS-0003-F/0005-F; and  
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer, CMS-0003-F/0005-F.

## VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258 which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules. The analysis in the Transactions Rule assumed that the adopted standards will be able to be implemented successfully by the industry. The changes adopted in this final rule are a result of industry analyses that showed certain minor modifications to the adopted standards would be necessary to permit full industry compliance with the standards.

These modifications make limited adjustments and corrections to the overall standards and would facilitate the congressional intent of implementation of national electronic standards. Thus, the impact analysis previously published, 65 FR 50350 through 50365, would reflect industry experience in implementing the changes adopted in this rule.

In relation to the prior impact analysis, this final rule imposes no additional burdens and creates no additional costs. All of the modifications adopted in this final rule and proposed in CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050) are required to facilitate successful implementation of the standards. Their implementation will, in fact, avoid costs that were not anticipated in the impact analysis of the Transactions Rule.

The 115 approved modifications to the standards included 48 maintenance changes (minor error corrections or clarifications), and 67 modifications to the standards. Details of these 67 modifications include—

- Changing the usage of data elements from “required” to “situational” (about 20 percent of changes);
- Removal of certain data elements (about 20 percent of changes);
- Allowing certain data elements to be reported via external code sets rather than data elements in the transaction (about 20 percent of changes); and
- Adding additional functionality to some transactions (about 40 percent of changes).

In particular, institutional and professional providers that have submitted ASCA compliance plans will not be required to retool systems and restructure current operations to accommodate the adopted NDC for reporting drugs and biologics on non-retail pharmacy standard transactions. Estimates reported to the NCVHS indicated that the cost of transitioning to NDCs on institutional claims could easily exceed an institution's cost for adopting all other transaction standards combined. While costs could vary depending on the size of the facility, hospitals estimate the minimum cost at \$200,000 per facility to switch from HCPCS codes to NDCs. The industry also estimates that typical physician practices may spend \$800 to as much as \$100,000 for practice management systems.<sup>2</sup> Although included for purposes of illustration, documentation to substantiate these estimates of the true costs for institutional providers of adopting the NDC as the code set

standard for transactions involving drugs and biologics was not provided. Consequently, we do not consider these to be reliable estimates of the true costs for institutional providers of adopting the NDC as the code set standard for transactions involving drugs and biologics. This final rule retracts the adoption of the NDC and does not adopt any standard medical code set for reporting drugs and biologics on nonretail pharmacy transactions. Institutional and professional providers can continue their current practices for reporting drugs and biologics on institutional and professional standard transactions.

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. On November 17, 2000, the Small Business Administration (SBA) published a final rule (65 FR 69432) changing the small business size standards for the health care industry. This SBA rule became effective December 18, 2000. The size standards that the SBA now uses are those defined by the North American Industry Classification System. Before that, the SBA used size standards as defined by the Standard Industrial Codes. The size standard is no longer a uniform \$5 million in annual revenues for all components in the health care sector. Rather, the size standard now ranges from \$6 million to \$29 million. The RFA for this final rule is linked to the aggregate RFA for all the Administrative Simplification standards that appeared in the Transactions Rule, which predated the SBA change. It is appropriate, for purposes of this final rule, to continue to use the \$5 million small business size standard that was in effect at the time of publication of the Transactions Rule. Maintaining this consistent definition for small business size minimizes confusion in the industry and does not adversely impact entities that were not considered small businesses according to the Transaction Rule definition. Nonprofit organizations are considered small entities. Small government jurisdictions with a population of less than 50,000 are considered small entities. Individuals and States are not considered small entities. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less in any one year. For purposes of the RFA, all retail pharmacies are considered to be small entities. We have determined that this final rule will not have a significant economic impact on a substantial number of small entities.

<sup>2</sup> Testimony from health care providers to the NCVHS on February 1, 2001.

This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final rule will not have an additional significant impact on a substantial number of small rural hospitals. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden, particularly on hospitals and other institutional providers, who will no longer be required to adopt the NDC for transactions involving drugs and biologics.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule will have no mandated consequential effect on State, local, or tribal governments, or on the private sector when using the Regulatory Impact Analysis for the Transactions Rule (65 FR 50350 through 50365) as a baseline.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule will not significantly affect the rights, roles, and responsibilities of States. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget (OMB).

## List of Subjects in 45 CFR Part 162

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, part 162 as follows:

## PART 16—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

**Authority:** Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

2. Section 162.900 is revised to read as follows:

### § 162.900 Compliance dates for transaction standards and code sets.

(a) *Small health plans.* All small health plans must comply with applicable requirements of subparts I through R of this part no later than October 16, 2003.

(b) *Covered entities that timely submitted a compliance plan.* Any covered entity, other than a small health plan, that timely submitted a compliance plan with the Secretary under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part no later than October 16, 2003.

(c) *Covered entities that did not timely submit a compliance plan.*

Any covered entity, other than a small health plan, that did not timely submit a compliance plan under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part—

(1) Beginning on October 16, 2002, and ending on October 15, 2003—

(i) For the corresponding time period; or

(ii) For the time period beginning on October 16, 2003.

(2) Beginning on and after October 16, 2003, for the corresponding time period.

3. Section 162.920 is revised to read as follows:

### § 162.920 Availability of implementation specifications.

A person or an organization may directly request copies of the

implementation standards described in subparts I through R of this part from the publishers listed in this section. The Director of the Office of the Federal Register approves the implementation specifications described in this section for incorporation by reference in subparts I through R of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications described in this paragraph are also available for inspection by the public at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC; and the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. Copy requests must be accompanied by the name of the standard, number, if applicable, and version number. Implementation specifications are available for the following transactions:

(a) *ASC X12N specifications.* The implementation specifications for ASC X12N standards may be obtained from the Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD, 20852–2116; Telephone (301) 949–9740; and FAX: (301) 949–9742. They are also available through the Washington Publishing Company on the Internet at <http://www.wpc-ed.com/>. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company,

004010X091A1 as referenced in § 162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in § 162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in § 162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in § 162.1302.

(8) The ASC X12N—276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in § 162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in § 162.1202.

(b) *Retail pharmacy specifications.* The implementation specifications for retail pharmacy standards may be obtained for a fee from the National Council for Prescription Drug Programs (NCPDP), 9240 E. Raintree Drive, Scottsdale, AZ 85260; Telephone (480) 477-1000; and FAX (480) 767-1042. They may also be obtained through the Internet at <http://www.ncpdp.org>. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in § 162.1102,

§ 162.1202, § 162.1302, § 162.1602, and § 162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(3) The National Council for Prescription Drug Programs (NCPDP) equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0, February 1, 1996, as referenced in § 162.1102, § 162.1202, § 162.1602, and § 162.1802.

4. Section 162.1002 is amended by—

A. Revising the introductory text to the section.

B. Redesignating paragraphs (a) through (f) as paragraphs (a)(1) through (a)(6).

C. In redesignated paragraph (a)(1), further redesignating paragraphs (1) through (5) as paragraphs (a)(1)(i) through (a)(1)(v).

D. In redesignated paragraph (a)(2), further redesignating paragraphs (1) through (4) as paragraphs (a)(2)(i) through (a)(2)(iv).

E. In redesignated paragraph (a)(3), further redesignating paragraphs (1) and (2) as paragraphs (a)(3)(i) and (a)(3)(ii).

F. In redesignated paragraph (a)(5), further redesignating paragraphs (1) through (7) as paragraphs (a)(5)(i) through (a)(5)(vii).

G. In redesignated paragraph (a)(6), further redesignating paragraphs (1) through (3) as paragraphs (a)(6)(i) through (a)(6)(iii).

H. Adding new paragraph (a) introductory text and paragraph (b).

The republication and additions read as follows:

#### § 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(a) For the period from October 16, 2002 through October 15, 2003:

\* \* \* \* \*

(b) For the period on and after October 16, 2003:

(1) The code sets specified in paragraphs (a)(1), (a)(2), (a)(4), and (a)(5) of this section.

(2) *National Drug Codes (NDC)*, as maintained and distributed by HHS, for reporting the following by retail pharmacies:

(i) Drugs.

(ii) Biologics.

(3) *The Healthcare Common Procedure Coding System (HCPCS)*, as

maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

5. Section 162.1102 is revised to read as follows:

#### § 162.1102 Standards for health care claims or equivalent encounter information transaction.

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0 February 1, 1996.

(Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

(b) For the period from October 16, 2002 through October 15, 2003:

(1) *Retail pharmacy drugs claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 1, (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. and Addenda to Health Care Claim: Dental, Version 4010,

October 2002, Washington Publishing Company, 004010X097A1.

(Incorporated by reference in § 162.920).

(3) *Professional health care claims*. The ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims*. The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

6. Section 162.1202 is revised to read as follows:

**§ 162.1202 Standards for eligibility for a health plan transaction.**

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *Retail pharmacy drugs*. The National Council for Prescription Drug Programs Telecommunications Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 0, February 1, 1996. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drug claims*. The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drugs*. The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1. (Incorporated by reference in § 162.920).

7. Section 162.1302 is revised to read as follows:

**§ 162.1302 Standards for referral certification and authorization transaction.**

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) For the period from October 16, 2002, through October 15, 2003: The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drug referral certification and authorization*. The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional referral certification and authorization*. The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010,

October 2002, Washington Publishing Company, 004010X094A1.

(Incorporated by reference in § 162.920).

8. Section 162.1402 is revised to read as follows:

**§ 162.1402 Standards for health care claim status transaction.**

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2002 through October 15, 2003: The ASC X12N—276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: The ASC X12N—276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1. (Incorporated by reference in § 162.920).

9. Section 162.1502 is revised to read as follows:

**§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.**

The Secretary adopts the following standards for the enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2002 through October 15, 2003: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1. (Incorporated by reference in § 162.920).

10. Section 162.1602 is revised to read as follows:

**§ 162.1602 Standards for health care payment and remittance advice transaction.**

The Secretary adopts the following standards for the health care payment and remittance advice transaction.

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *Retail pharmacy drug claims and remittance advice*. The NCPDP Telecommunication Standard Implementation Guide, Version 5

Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996.

(Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care claims and remittance advice.* The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: *Health care claims and remittance advice.* The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in § 162.920).

11. Section 162.1702 is revised to read as follows:

**§ 162.1702 Standards for health plan premium payments transaction.**

The Secretary adopts the following standards for the health care premium payments transaction.

(a) For the period from October 16, 2002 through October 15, 2003: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products,

Version 4010, October 2002, Washington Publishing Company, 004010X061A1. (Incorporated by reference in § 162.920).

12. Section 162.1802 is revised to read as follows:

**§ 162.1802 Standards for coordination of benefits information transaction.**

The Secretary adopts the following standards for the coordination of benefits information transaction.

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0, February 1, 1996. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard

Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in § 162.920).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 31, 2003.

**Tommy G. Thompson,**  
*Secretary.*

[FR Doc. 03–3876 Filed 2–13–03; 3:07 pm]

**BILLING CODE 4120–01–P**



# Federal Register

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**Thursday,  
February 20, 2003**

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## **Part III**

## **Department of the Interior**

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**Minerals Management Service**

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**30 CFR Part 250**

**Oil and Gas and Sulphur Operations in  
the Outer Continental Shelf—Oil and Gas  
Drilling Operations; Final Rule**

**DEPARTMENT OF THE INTERIOR****Minerals Management Service****30 CFR Part 250**

RIN 1010-AC43

**Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Oil and Gas Drilling Operations****AGENCY:** Minerals Management Service (MMS), Interior.**ACTION:** Final rule.

**SUMMARY:** This final rule restructures the requirements for oil and gas drilling operations on the Outer Continental Shelf (OCS), adds some new requirements, and converts the regulations into plain language. The restructuring of the rule follows the logical sequence of obtaining approval to drill a well and conducting drilling operations. The final rule also removes overly prescriptive requirements and updates requirements to reflect changes in drilling technology. Restructuring the drilling requirements makes the regulations easier to read, understand, and follow. The technical changes will help ensure that lessees conduct operations in a safe manner.

**EFFECTIVE DATE:** The rule is effective March 24, 2003. The incorporation by reference of publications listed in the regulation is approved by the Director of the Federal Register as of March 24, 2003.

**FOR FURTHER INFORMATION CONTACT:** William Hauser, Engineering and Operations Division, at (703) 787-1613.

**SUPPLEMENTARY INFORMATION:** On June 21, 2000, we published a Notice of Proposed Rulemaking (65 FR 38453), titled "Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Oil and Gas Drilling Operations" to revise the subpart D regulations of part 250, with exception of the regulations on Hydrogen Sulfide under 30 CFR 250.417. The proposed rule had a 90-day comment period that we extended to 120 days on July 27, 2000 (65 FR 46126). The extended comment period closed on October 19, 2000.

**Differences Between Proposed and Final Rules Not Directly Related to Comments**

In addition to changes we made to the final rule in response to public comments, we reworded several sections to further clarify the requirements. We also changed several section titles to better reflect the intent of the sections. The following are the changes by section:

- Section 250.403—We divided the requirements contained in the table in this section into three new sections. We believe this change provides a better understanding of the requirements. The new sections are:

250.404 What are the requirements for the crown block?

250.405 What are the safety requirements for diesel engines on a drilling rig?

250.406 What additional safety measures must I take when I conduct drilling operations on a platform that has producing wells or has other hydrocarbon flow?

- New § 250.405—We added engines on escape capsules to the list of diesel engines that you do not have to equip with an air intake device. We believe that this device should not be required on an escape capsule. We also revised paragraph (b) by adding the term "remote" to manual air intake shutdown device so that the requirement means the same as the previous requirement. Paragraph (b) now reads as follows: "For a diesel engine that is continuously manned, you may equip the engine with either an automatic or remote manual air intake shutdown device;"

- New § 250.406(b)—This paragraph applies to shutting in producing wells during the movement of a drilling rig on and off a location. We clarified the requirements of this section in response to comments from the Offshore Operators Committee (OOC) (see discussion in OOC comments section). We want to further clarify in the preamble of this rule that the same requirements to shut in producing wells would apply when a lessee moves in a drilling rig or coiled tubing unit to complete or workover a well. We plan to clearly state these requirements for completion and workover activities in revisions of subparts E and F that we anticipate proposing.

- Sections 250.408 and 250.409—We added two new sections to address the use of alternative procedures or equipment during drilling operations and obtaining departures from the drilling regulations. We made this revision to clearly state the procedures for using alternative procedures or equipment and for obtaining departures from the drilling regulations. We also removed phrases similar to "or as otherwise approved by the District Supervisor" throughout the rule because you may request a departure or the use of alternative procedures or equipment with respect to any of the drilling requirements prescribed in the rule, provided the rationale is appropriate.

- Section 250.414—We added an introductory sentence to this section

which states that the drilling prognosis must include a brief description of the procedures that you will follow in drilling the well. That description includes the nine items listed (a) through (i) in this section and any other events or procedures that are out of the ordinary for drilling activities. We also moved the paragraph on listing and describing departures or requests to use alternative procedures and equipment to this section.

- Section 250.421(d)—We revised this paragraph to read as follows: "As a minimum, you must cement the annular space 500 feet above the casing shoe and 500 feet above each zone to be isolated." We inserted the phrase "500 feet above" before "each zone" to ensure that there was no confusion about cementing requirements for the intermediate casing. This clarification is consistent with the current regulations.

- Section 250.424—We converted the requirements for pressure testing casing into a table. This will make the requirements easier to understand.

- Section 250.427—We clarified the requirement for when you must conduct a pressure integrity test after drilling new hole below the casing shoe. The original requirement stated a maximum amount that you could drill before conducting the test (50 feet). The revised requirement has both a minimum (10 feet) and a maximum (50 feet) amount that you could drill before conducting the test. This will remove any confusion about how much new formation you must drill before conducting the test.

- Section 250.465(a)(3)—We revised this paragraph to require the submittal of a plat certified by a registered land surveyor when you determine the well's final surface location, water depth, and the rotary kelly bushing elevation. This requirement is consistent with the current regulations. The certified plat serves a useful purpose because it provides certainty to the well's location. In some instances, submittals of non-certified plats or reliance upon the planned location plat provide only a rough idea of where the well may be located.

**Changes to Drilling and Well Forms Not Related to Comments**

Through a separate process, MMS revised the associated 30 CFR 250, subpart D, drilling and well forms MMS-123, MMS-123S, MMS-124, MMS-125, and MMS-133. We are conducting the form revisions in compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), and as part of our efforts to implement the Government Paperwork

Elimination Act and streamline data collection. The revised forms were published for comment in the **Federal Register** on May 1, 2002 (67 FR 21718). In addition to revising some of the data elements on each form, we changed the titles of forms MMS-124 (Sundry Notices and Reports on Wells changed to Application for Permit to Modify), MMS-125 (Well Summary Report changed to End of Operations Report), and MMS-133 (Weekly Activity Report changed to Well Activity Report). In accordance with the PRA, we submitted the revised forms to the Office of Management and Budget (OMB) for approval. The OMB approved the use of the new forms in October 2002 and these final regulations incorporate the changes to the forms.

### Comments on the Rule

We received 11 sets of comments on the proposed rule and other considerations for drilling regulations. The comments came from four oil and gas lessees/operators (Chevron USA Production Company, Shell Exploration & Production Company, Torch Operating Company, and Mariner Energy), two drilling contractors (Noble Drilling Services and Rowan Companies), three trade organizations (American Petroleum Institute (API), OOC, and International Association of Drilling Contractors (IADC), one consultant (West, Inc.), and one private citizen (James E. May). You may view these comments and the Notice of Proposed Rulemaking (NPR) on the MMS Web site at address: <http://www.mms.gov/federalregister/PublicComments/rulecomm.htm>. The OOC and IADC provided the most comprehensive sets of comments on the proposed rule. Three of the operators and both drilling contractors fully supported the comments of their respective trade organizations and provided additional comments. The API noted that it worked with OOC in preparing detailed comments on the rule and fully supports the comments submitted by OOC. The OOC presented its comments on specific sections of the rule in a table that identified the section, suggested changes, and provided rationale for those changes. We found this to be an informative format for reviewing comments and have used that format to respond to OOC's comments.

We organized our responses to comments on the NPR into three sections. These sections address the following topics:

I. General comments and comments on other considerations for drilling regulations (*i.e.*, need for regulations on

the use of coiled tubing, mandatory use of automated pipe handling systems);

II. Comments on specific sections that OOC did not address in its comments; and

III. OOC's comments on specific sections (table format).

### I. General Comments and Responses

- *Comment:* The use of Lessees/Operators/Contractors relates better to these regulations than the use of "I" and "you."

*Response:* We disagree. The use of "I" and "you" in the regulations essentially replaces the terms "lessees, operators, and contractors." It is much easier to say "you must" versus the "lessee/operator/contractor must."

- *Comments on Incorporating API Recommended Practice (RP) 53, Recommended Practice for Blowout Prevention Equipment Systems for Drilling Wells (API RP 53) into the regulations:* One commenter stated that the incorporation of specific sections of API RP 53 is appropriate because incorporation of the entire document would lack the specificity needed for the regulations. Another commenter recommended that the entire contents of API RP 53 should be incorporated by reference to provide overall guidelines for blowout preventer (BOP) systems.

*Response:* MMS has incorporated specific sections of API RP 53 into the regulations as proposed. The primary reason for selecting specific sections was to provide needed specificity to the existing requirements. However, API RP 53 provides excellent guidelines for operating and maintaining BOP systems, and MMS will consider incorporating the entire document in a future revision of the drilling regulations.

MMS will also consider the incorporation of other API drilling documents. MMS recently contracted with West, Inc. to review and compare three API Recommended Practices to MMS regulations and IADC's Deepwater Guidelines. The three Recommended Practices are:

1. 16E—Design of Control Systems for Drilling Well Control Equipment;
2. 64—Diverter System Equipment and Operations; and
3. 16Q—Design, Selection, Operation, and Maintenance of Marine Drilling Riser Systems.

West, Inc.'s complete report is available on the MMS Web site at <ftp://www.mms.gov/TARProjects/380/380AA.pdf>.

- *Comments on Automated Pipe Handling Systems:* This topic generated many comments, most of which disagreed with requiring automated pipe handling systems. Comments

against requiring these systems included the following:

- Little data exist to support the theory that automated pipe handling systems measurably improve personnel safety;
- Automated pipe handling systems create new safety hazards (*i.e.*, new pipe racking systems have introduced additional tripping hazards to rig floor personnel which have resulted in lost time incidents);
- Costs (including capital and out-of-service time) to retrofit the drilling units would not be justified considering the perceived safety benefits;
- Some drilling units could not be retrofitted due to space limitations and/or due to the added weight of the automated pipe handling equipment; and
- Reliability is an issue with some automated systems

Other comments questioned if automated systems meant totally automated pipe handling systems or just a subset of automated rig floor equipment such as iron roughnecks, spinners, and power slips. Commenters also asked if operations would have to be suspended if the automated systems were not available due to downtime. While the vast majority of the comments were against requiring automated systems, one comment said that MMS should require some automated rig floor equipment, but those requirements should be flexible and a practical application of existing technology.

*Response:* MMS appreciates the comments industry has provided on this topic, and we now have a better understanding of how a requirement for an automated pipe handling system could impact the drilling industry and drilling operations. One of the purposes for raising this issue in the preamble of the proposed rule was to elicit this information. This final rule does not include any requirements for automated pipe handling systems or automated rig floor equipment. Nor is MMS proceeding with any proposed regulations on these systems at this time.

- *Comments on Best Cementing Practices:* Most comments were along the lines that best cementing practices should be used where possible, but that specific practices should not be mandated by specific requirements. OOC stated that the complexity of cementing operations and a variety of cements are not good candidates for prescriptive requirements. One suggested approach was to supplement current cement compressive strength and height requirements with regulatory



guidelines that would allow the needed flexibility to determine which practices are applicable to the particular down-hole environment. Several commenters noted that they are participating in an API/International Standards Organization (ISO) Cementing Committee to discuss best cementing practices with MMS and develop appropriate guidance for best cementing practices.

*Response:* MMS will continue with the cementing requirements as proposed in this rule. These requirements are similar to the requirements that were in the previous regulations. As noted in the above comment, MMS is participating in the API/ISO Cementing Committee and will work with the committee to develop appropriate guidelines for cementing practices. We may take further regulatory actions after the committee completes its work.

- *Comment:* One commenter said that the proposed regulations do not protect the environment enough, and that MMS is aware of a substantial number of OCS wells that are leaking oil to the surface and between formations. The commenter asserted that the proposed rule aggravates this problem by using the term "cementing." The commenter asked why MMS allows oil companies to use cement and not other sealants.

*Response:* MMS believes that the proposed regulations for cementing wells provide adequate protection to the environment. MMS also believes that there are opportunities to improve cements and cementing practices so, over the years, MMS has participated in a number of research projects that examined ways to improve cementing in oil and gas wells. We continue to participate in cementing research efforts and other efforts, such as the API/ISO Cementing Committee, to ensure that cementing technology continues to advance. MMS requires industry to use cement to seal formations and plug wells because it works; however, we will allow industry to use other sealants if they provide equal or better performance than cement. In the past, these generic requests to expand the rules to allow the use of other "sealants" have sometimes actually been attempts to get approval to use clays, gels, and other low compressive strength, non-hardening compounds.

MMS knows of only a few abandoned wells that have leaked after permanent abandonment. When we become aware of an abandoned well that is leaking, we require the operator of record to take immediate action to remedy the situation. Also, to further our awareness of potential leaking abandoned wells, MMS has recently sponsored research to

identify leaking abandoned wells by using remote sensing.

- *Comment on regulating coiled tubing drilling:* The OOC commented that MMS was taking the correct approach by not proposing specific regulations for coiled tubing drilling. OOC agreed that a better understanding of these operations and the amount of activity that is likely to take place on the OCS was necessary before drafting regulations. OOC stated that the existing/proposed provisions in subpart D, coupled with the District Supervisors' authority to approve alternative techniques and procedures, adequately addresses the regulatory mandates. OOC also supported the use of API RP 5C7 for Coiled Tubing Operations in Oil and Gas Well Services (API RP 5C7) as a guideline when preparing the appropriate regulations.

*Response:* MMS will continue to monitor the use of coil tubing on the OCS and will propose additional regulations as needed.

## II. Comments on Specific Sections That the OOC Did Not Address in Its Comments

- *Comment on § 250.404 What mobile drilling unit movements must I report?* This requirement should be waived after commencement of the first well on a platform.

*Response:* We have revised this section to clearly state what rig movements the lessee must report to MMS. This includes the movement of both mobile offshore drilling units (MODU) and platform rigs. We need this information to ensure that our inspectors have the correct information in hand when they arrive at a platform rig to perform an inspection. MMS also needs to know the movement of drilling rigs, coiled tubing units, and snubbing units on and off locations for completion and workover activities, so we will clarify these requirements in revisions of 30 CFR 250, subparts E and F that we anticipate proposing.

- *Comment on § 250.404 What mobile drilling unit movements must I report?* The proposed rule duplicates U.S. Coast Guard (USCG) requirements to report MODU movements under 33 CFR parts 67 and 72. While the proposed rule affects the lessee, the MODU owner is reporting the required information to the USCG. MMS and USCG should share this information so that you can eliminate a reporting requirement.

*Response:* MMS needs MODU movement information 24 hours in advance of movement to plan our rig inspections. USCG's timing requirements for rig movement notice

do not meet our rig inspection planning needs. Based on similar comments during the process to develop the new MMS form to report rig movements, we incorporated "optional" information needed by the USCG so that the form could be used for reporting to either agency.

- *Comment on § 250.412 What requirements must my plat meet?* The lessee or operator should be allowed to decide how to report well location.

*Response:* MMS must have the coordinates reported in a consistent manner to ensure that the exact well locations are known.

- *Comment on § 250.417 What information must I provide if I intend to use a mobile drilling unit to drill a proposed well?* Paragraph (c) may require a third-party review of a MODU's design by a Certified Verification Agent. This review may involve the MODU's structural components or integrity which would be in direct conflict with the December 1998 Memorandum of Understanding (MOU) between MMS and USCG. Under that MOU, the USCG has full responsibility for the structural integrity of MODUs.

*Response:* This is not a new requirement (see current regulation at § 250.401(a)(3)). The purpose of this requirement is to address the possible unique drilling unit that a lessee may propose to use in a frontier area. Our intent is to ensure that proper design reviews are conducted before the unit's use at a proposed frontier location. When this situation occurs, MMS will confer with the USCG concerning the drilling unit design and its use at the specified location. If the USCG design review meets our concerns, then MMS will not require additional design reviews. If additional reviews are needed, the District Supervisor will use this requirement to address necessary information. We have revised this paragraph to clarify that this requirement applies only to frontier areas where the drilling unit design is unique or the unit has not been proven for use in the proposed environment. MMS will follow the 1998 MMS/USCG MOU to the extent possible to minimize duplicating design requirements of both agencies.

- *Comments on § 250.417(h) and 250.418(a).* The IADC and two drilling contractors commented that these paragraphs indicate that MMS is maintaining files of rig-specific information. While such action by MMS is clearly in a drilling contractor's interest, they could not find the authority for MMS to maintain files on individual drilling rigs or to transfer this

information between the files of lessees/operators.

The commenters were frustrated that MMS interprets its legislative authority as precluding direct contact between the agency and rig owners. They are convinced that direct communication between MMS and MODU owners/operators is permissible and advisable. They recommended that MMS should review and approve the use of MODUs and platform rigs on a regional basis. This would eliminate what appears to be a repetitive and non-productive review of identical drilling rig specifications by its District Offices.

*Response:* The lessee/operator must submit a detailed description of the drilling unit including specifications for all its components, regardless of whether it is a MODU, with the Application for Permit to Drill (APD) a new well. MMS may communicate with the contractor; however, it is the responsibility of the lessee/operator to submit the required information to MMS. Drilling unit documents are part of the APD and are maintained in well data files by MMS.

MMS does maintain limited files (work history, where and when built, depth capability and water depth, safe welding area approval, USCG certificate, etc.) on drilling rigs in the Gulf of Mexico (GOM). This information is useful as a cross reference of submitted information and when the lessee/operator does not include rig-specific information with the APD or sundry notice. Such information is used only within MMS (although much is readily available on the company Web sites) and is not transferred between lessees/operators. MMS only requires submission of this basic rig information and job-specific information such as BOP sketch, diverter sketch, and similar related information. This job-specific information can change due to rental BOPs and diverters or procedural changes.

MMS drilling and workover engineers, as well as inspectors, regularly talk with rig owners, superintendents, pushers, drillers, and operator personnel about rig conditions, pollution, new equipment, training, accidents, etc. Only those items specific to a location, items that must be renewed regularly (certificates), and training are reviewed for each APD or sundry notice, and even some of these are only checked by the inspector once work has started. It is up to the lessee/operator via their contracts to require that rig owners conform to MMS regulations.

• *Comment on § 250.422(b) When may I resume drilling after cementing?*

A commenter said that the waiting time before removing the diverter is not necessary.

*Response:* MMS disagrees. Determining the time when it is safe to remove the diverter is just as important as determining the time for the BOP because several incidents have involved early removal of the diverter.

• *Comment on § 250.423(f) How must I remedy cementing and casing problems and irregularities?* A commenter suggested that field-specific rules rather than general rules should apply to the requirement that you must have at least two cemented casing strings to produce a well.

*Response:* Field rules could apply if they are established in accordance with § 250.463.

• *Comment on § 250.424(b) What are the requirements for pressure testing casing?* The requirement should allow an exception for horizontal cementing applications.

*Response:* To obtain an exception for pressure testing casing, you may request approval from the District Supervisor to use alternative procedures (§ 250.408) or obtain a departure (§ 250.409). The District Supervisor will evaluate these requests on a case-by-case basis. Therefore, we did not include an exception for horizontal cementing applications in the requirements.

• *Comment on § 250.430 When must I install a diverter system?* MMS shouldn't require installation of a diverter when returns are taken at the ocean floor (i.e., no casing/riser on which to install a diverter).

*Response:* The regulations require the installation of a diverter system before you drill a conductor or surface hole. If you want to drill a conductor or surface hole without a diverter, you must include this procedure in your APD and obtain approval from the District Supervisor.

• *Comment on § 250.431 What are the diverter design and installation requirements?* MMS should consider removing statements from the regulations that are not auditable, such as minimizing the number of turns or maximizing the radius of curvature of turns for diverter lines for bottom-founded drilling units. MMS could reference industry standards such as API RP 53 to better define what is required.

*Response:* MMS will continue with the current performance standards of minimizing the number of turns and maximizing the radius of curvature of turns for diverter lines. We used these standards in past regulations because it is difficult to prescribe measures that will work for each drilling unit.

However, in future rulemakings, we will consider incorporating additional standards to address some of the requirements that are difficult to audit.

• *Comment on § 250.433 How must I test the diverter system after installation?* MMS should allow for testing diverters on a 14-day frequency.

*Response:* MMS conducted several studies on BOP performance before we revised the regulations to allow for testing BOPs on a 14-day frequency. We made sure that extended testing frequency would not compromise safety during drilling operations. MMS will not consider revising the testing frequency for diverters until research shows that an extended testing frequency will not compromise safety.

• *Comments on § 250.441 What are the requirements for a surface BOP stack?*

This section proposed that each surface BOP stack must have at least one preventer equipped with blind-shear rams within 1 year after the effective date of this final rule. This proposed requirement prompted many comments. Four commenters opposed the proposed requirement and provided reasons for their opposition. IADC provided the most comprehensive comments against this proposed requirement. A fifth commenter stated that it also opposed the proposed requirement and said it supported IADC's comments. Three other commenters stated that they supported IADC's and OOC's comments but they did not specifically mention the proposed requirement for blind-shear rams. Two other commenters also provided comments on this proposed requirement and those comments are included below.

A summary of all the comments on the proposed requirements for blind-shear rams follows:

—IADC plotted the incidents over the 20-year period, and its graph showed that the incident rate where blind-shear rams might have prevented a serious blowout is approaching zero. IADC believes that this trend is sufficient to negate the need for MMS to mandate the installation of the blind-shear rams. Possible activities that lead to this declining trend include:

- Greater attention being paid to safety management as a result of Safety and Environmental Management Programs and other initiatives;

- Continuous improvement in well control methods and equipment; and

- Greater attention to the quality of well control training

—IADC also stated the following:

- Successful operation of blind-shear rams (intentional or not) permanently forecloses other well control options;
- MMS did not consider the consequences of inadvertent operation or malfunction of the rams;
- MMS underestimated the number of surface BOP stacks that would need blind-shear rams by 50 percent, thus underestimating the costs by 50 percent; and
- If the final rule requires the blind-shear rams, then industry will need an additional 2 years to comply with the requirement.

—Operating limits of blind-shear rams are frequently unclear for some drilling operations due to pipe grades, mud weights, and wellbore pressures, and that consideration should be given to ensure that these limits are clear

*Response:* MMS continues to believe that having blind-shear rams in a surface BOP stack is an important safety measure. Blind-shear rams offer an additional opportunity to control the well in a difficult situation. We believe that these rams provide the last line of defense against a blowout when drill pipe or tubing is hung in the BOP stack and there are difficulties in installing or closing the drill string safety valve, inside BOP, or tubing safety valve. Successful operation of the blind-shear rams may prevent damage to the drilling rig, platform, or other facilities, and prevent injuries or the loss of life.

The IADC and industry provided a number of comments on why MMS should not require blind-shear rams in surface BOP stacks. Their most compelling reason against requiring blind-shear rams is industry's recent performance concerning incidents where blind-shear rams might have prevented or minimized a blowout. Those comments are correct in that industry's recent performance is good, especially when compared to the relatively high number of incidents that occurred in the early 1980's. However, there have been three serious incidents where blind-shear rams may have prevented a blowout since 1996 (two incidents occurred in 2001). A brief description of each event follows:

Incident 1—occurred on Platform A, Eugene Island Block 380, on January 24, 1996. During completion operations, the well began to flow while the tubing was

extended above the BOP stack. The crew tried to stab the top drive into the top of the tubing but the flow had increased and they were unable to make the connection. The driller closed the blind rams to reduce the flow but that did not help. Gas began to flow out of the top of the tubing, so the drilling crew closed the pipe rams and annular preventer and evacuated the rig floor. During the evacuation of the rig and platform, the well caught fire. The fire destroyed the rig substructure and derrick and severely damaged other parts of the rig. Fortunately there were no injuries or pollution. After investigating the accident, MMS' investigation team recommended that blind-shear rams should be required in surface BOP stacks. The investigation report can be found on our Web site at: [http://www.gomr.mms.gov/homepg/offshore/safety/acc\\_repo/98-0012.pdf](http://www.gomr.mms.gov/homepg/offshore/safety/acc_repo/98-0012.pdf).

Incident 2—occurred on Platform A Eugene Island Block 277, on July 6, 2001. While killing a kick that occurred during workover operations, the pressure safety valve on the mud pump ruptured. The well then flowed uncontrolled through the drill pipe and the ruptured pressure safety valve. The area around the rig equipment and drill floor became inundated with a hazardous accumulation of gas and formation sand which forced all personnel to evacuate to a standby boat. Fortunately there were no injuries and only major damages to the rig. The investigation report can be found on our Web site at: [http://www.gomr.mms.gov/homepg/offshore/safety/acc\\_repo/2002-040.pdf](http://www.gomr.mms.gov/homepg/offshore/safety/acc_repo/2002-040.pdf).

Incident 3—occurred on a jack-up drilling rig drilling in Brazos Block 417 on July 13, 2001. During drilling operations, the well began to flow while the crew was making up the next joint of drill pipe in the mouse hold. The rig floor safety valve was stabbed but would not close with two men applying torque to the handle. Both men were burned on their arms and back by the hot mud. Because of the high temperature of the mud, the men had to put on slicker suits and were sprayed with water to continue working on the rig floor. A third man assisted in the attempt to close the valve and sufficient torque was applied to the closing handle to shear it off at the key opening of the valve. Mud continued flowing out of the drill pipe

until it was shooting over the top of the derrick. Gas began to flow with the mud from the drill pipe and it became unsafe to work on the rig floor. The crew was ordered to abandon the rig. After the rig was abandoned, it was discovered that the night supervisor was missing. The Coast Guard searched for two days but the night supervisor was never found. The BOP stack, casing and drill pipe were damaged by high pressure gas and sand that flowed from the well. The rig was also damaged by the gas and sand flow. The investigation report can be found on our Web site at: [http://www.gomr.mms.gov/homepg/offshore/safety/acc\\_repo/2002-062.pdf](http://www.gomr.mms.gov/homepg/offshore/safety/acc_repo/2002-062.pdf).

In these incidents, the drilling crews had run out of options to control the well and were forced to abandon the rig. We believe that the injuries, the fatality, and rig damages could have been avoided if blind-shear rams were in the BOP stack and were closed prior to evacuating the rig. Similar incidents have occurred during drilling, workover, and completion operations in the past, and blind-shear rams stopped the blowout. Similar incidents are very likely to occur in the future.

In the preamble of the proposed rule, MMS stated that it had reviewed the blowouts that have occurred since 1977 and found at least 12 incidents where blind-shear rams had helped or could have helped control the situation. Upon closer review of our records, we have identified 24 incidents where blind-shear rams either helped control a blowout or may have helped prevent a blowout (these records include MMS's database, memoranda, accident reports, investigations, operator letters, and operator investigations). The table below gives the date, location, and a brief description of each of those incidents. There were 10 fatalities, 23 injuries, 3 rigs destroyed, and 9 rigs damaged during those incidents. Furthermore, six of the investigation reports recommended that blind-shear rams be installed in surface BOP stacks. Considering that the installation of blind-shear rams provides an additional means of controlling a blowout and can help prevent future injuries, fatalities, and protect property and the environment, MMS will require the installation of blind-shear rams in surface BOP stacks.

Date	Block/lease #	Description of incident
6/23/77 .....	Eugene Island 307, G 2110 .....	Blowout while running dual completion string. Tubing was 84 feet above the drill floor when well began blowing through the tubing. The tubing safety valve could not be installed so blind rams were closed but only crimped the tubing. Crew evacuated the rig safely. The blowout was controlled later that day. The Investigation Report recommended that the U.S. Geological Survey require shear rams on all BOP stacks.

Date	Block/lease #	Description of incident
7/20/77 .....	West Cameron 110, OCS 081 ..	Blowout occurred during workover operations. Well began to flow while pulling out of the hole. Drill string safety valve was installed but could not be closed. Blind rams were closed to restrict the flow but had no effect. There were no injuries. Well Control Team secured well 4 days later.
11/26/77 .....	Eugene Is. 307 G, 2110 .....	Well blew out while running into the hole during completion operations. All of the BOP's were closed but the well continued to flow. The flow was too great to stab the drill string safety valve. After 6 hours of attempting to diminish the flow through the drill pipe, the crew was able to install and close the drill string safety valve.
8/4/78 .....	Grand Isle 41, G 0129 .....	Blowout occurred during completion operations. Drill string safety valve could not be closed after well began to flow. After 15 minutes, the driller regained control of the well by closing blind-shear rams. There were no injuries.
3/5/79 .....	S. Marsh Island 281, G 2600 ...	While attempting to correct lost returns and stuck pipe problems, the well began to flow. The crew could not close the drill string safety valve when the well kicked the final time. There were eight fatalities and considerable damage to rig. The USCG Investigation Report (Oil & Gas Journal, p. 148, Nov. 17, 1980) concluded that shear rams could prevent similar casualties in the future.
8/24/80 .....	Vermilion 348, G 2271 .....	The well kicked while making up gravel pack assembly. The blind and pipe rams were closed on 4½" pipe portion of gravel pack assembly but did not seal the well. The drilling rig and portion of platform were destroyed. There were four minor injuries in the crew evacuation. The well bridged 37 days later.
1/12/81 .....	High Island 38, G 0477 .....	Blowout occurred while circulating out a kick. The well blew out through the neck on the swivel. The lower kelly cock was left 12 feet above the drill floor and was not closed. The blowout lasted approximately 12 hours, catching fire towards the end of the incident. Three people suffered overexposure after the evacuation and one later died.
7/26/81 .....	South Pelto 18, G3589 .....	Blowout during completion operations. While circulating mud, the well kicked. Crew closed upper kelly cock but it leaked. Operator closed blind-shear rams and evacuated platform. Gas leaked through the blind-shear rams but the rig never caught fire. Well was controlled 4 days later. One person suffered a broken leg and bruises during the evacuation.
10/5/81 .....	Eugene Island 273, G 0987 .....	Blowout occurred when the tubing parted during completion operations. The well was controlled after 38.5 hours by installing and closing blind-shear rams. The Investigation Report recommended that BOP stacks have blind-shear rams for completion operations. There were no injuries during the evacuation.
11/28/81 .....	Viosca Knoll 900, G 2445 .....	Blowout occurred during workover operations. The well kicked while pulling out of the hole. The BOPs were closed, but the flow through the drill string was too great to stab the drill string safety valve. The blowout lasted 24 hours. There was some pollution but no injuries and minimal damages.
4/19/82 .....	Galveston 391, G 3740 .....	Blowout occurred while completing the well. A drill string safety valve could not be installed because the drill pipe was above the monkey board. Well bridged over in 3 hours. There were no injuries and only minimal damage to the platform and rig.
5/15/82 .....	S. Marsh Island 155, G 4110 ...	While circulating a kick, an explosion and fire occurred under the rig floor and at the shale shaker. Blind-shear rams were activated and the well was shut in. Three people suffered minor injuries during the evacuation.
7/14/82 .....	West Cameron 65, G 2825 .....	Fishing operation when well began to kick. While attempting to control kick, the stand pipe blew out and the drilling crew could not close either of the kelly valves. Jackup rig was destroyed and the blowout continued for 57 days. There were no injuries.
12/17/82 .....	West Delta 70, G 0182 .....	Blowout occurred while working over well with a snubbing unit. Blowout pushed top of workstring to a point 30 feet above the highest object on the platform. Blowout was stopped after repeated attempts to function the shear rams.
10/20/83 .....	Eugene Island 10, G 2892 .....	While controlling a kick during a workover, gas began to leak from the threads in the cross-over sub and the drill string safety valve. The leak increased as the valve was closed, forcing the abandonment of the rig. The well was killed 6 days later. There was major damage to the rig but no injuries.
12/3/85 .....	West Cameron 648, G 4268 .....	Blowout during workover. Crew unable to stab workstring safety valve into the workstring when fluid began flowing. Three people were injured trying to stab the safety valve. The rig was destroyed and the platform heavily damaged by fire. The blowout lasted 47 days. The Investigation Report recommended that Order 6 be revised to require blind-shear rams in BOP stack during workovers.
3/20/87 .....	Vermilion 226, G 5195 .....	Blowout during completion activities. Blowout through the drill pipe and drill string safety valve failed. The well control team killed the well by installing blind-shear rams and shutting in the well. There were no injuries and only minor damage during the 3-day blowout. The Accident Investigation Report recommended the installation of blind-shear rams in BOP stacks.
5/30/90 .....	Brazos A-23, G 3938 .....	Blowout occurred during testing operations. The blind-shear rams were closed but failed as the rig was being jacked up to clear tubing from the blind rams. Blind rams were closed but gas flowed until well control team killed the well. There were no injuries and only minor damages during the 2-day blowout.
9/9/90 .....	Eugene Island 296, G 2105 .....	During workover operations, well began to flow through tubing after running one stand of collars and one stand of tubing into the well. Crew made at least four unsuccessful attempts to install full opening safety valve. The BOPs were closed but did not stop the blowout. There were eight injuries and rig damage during the 4-day blowout.

Date	Block/lease #	Description of incident
1/24/96 .....	Eugene Island 380, G 2327 .....	During completion operations, the well began to flow while the tubing was extended above the BOP stack. Crew tried to stab the top drive into the top of the tubing but the flow prevented the connection. The driller closed the blind rams to reduce the flow but that did not help. When gas began to flow out of the top of the tubing, the drilling crew closed the pipe rams and annular preventer and evacuated the rig. During the evacuation of the rig and platform, the well caught fire. Fire destroyed the rig substructure and derrick and severely damaged other parts of the rig. MMS investigation report recommended that blind-shear rams be required in surface BOP stacks. (incident 1 in above discussion).
5/31/97 .....	East Cameron 83, G 8641 .....	Blowout during completion operations. Well control team replaced pipe rams with blind-shear rams but found that the tool joint was opposite the rams. There were no injuries, pollution, or fire. Well was out of control for 19 days.
12/2/99 .....	SM58, G 01194 .....	Blowout occurred while running a gravel pack assembly during completion activities. The gravel pack was across the BOP stack when the well began to flow. The BOP's were closed but did not stop the blowout. The well bridged over the next day.
7/6/01 .....	Eugene Island 277, OCS-G 10744.	Blowout occurred during a workover operation. Well flowed uncontrolled through the drill pipe and ruptured pressure safety valve on the mud pump. The area around the rig equipment and drill floor became inundated with a hazardous accumulation of gas and formation sand thus forcing all personnel to evacuate to a standby boat. There were no injuries and only minor damages to the rig. (incident 2 in above discussion).
7/13/01 .....	Brazos 417, OCS-G 22190 .....	Blowout occurred during drilling operations. The well kicked and flowed up the drill pipe. The rig floor safety valve was stabbed but would not close with two men applying torque to the handle. Both men were burned on their arms and back by the hot mud. Because of the high temperature of the mud, the men had to put on slicker suits and were sprayed with water to continue working on the rig floor. The crew was ordered to abandon the rig. After the rig was abandoned, it was discovered that the night supervisor was missing. The Coast Guard searched for two days but the person was never found. The BOP stack, casing and drill pipe were damaged by high pressure gas and sand that flowed from the well. The rig was also damaged by the gas and sand flow. (incident 3 in above discussion).

IADC commented that we underestimated the number of blind-shear rams by approximately 50 percent (80), thus underestimating the costs by 50 percent. We have reexamined the number of rams that industry would have to purchase and found that of the rigs currently active or ready to work, 100 surface BOP stacks did not have blind-shear rams. When rigs temporarily taken out of service are included, 170 sets of blind-shear rams would be needed. Part of our low estimate was due to the increased drilling activity since we prepared the proposed rule and part was due to a low estimate of the number of blind-shear rams already

installed in surface BOP stacks. Our recent review found that at least 30 sets of blind-shear rams are currently installed in surface BOP stacks.

MMS made two assumptions when estimating the cost of upgrading existing surface BOP stacks to include blind-shear rams. First, it was projected that all rigs active or ready to work would remain in service for more than the next 3 years. Second, one-half of the rigs temporarily taken out of service would be placed back into long term service over the next 3 years. Increasing the number of blind-shear rams needed to comply with this requirement to 135 sets will raise costs estimated in the

proposed rule from \$14,000,000 to \$14,175,000. The original cost per set of blind-shear rams was overstated (\$175,000), and has been reduced (\$105,000) according to information obtained recently from BOP manufacturers. Given the number of rams that industry will have to purchase, MMS has allowed a 3-year timeframe for installing the rams versus the 1-year timeframe identified in the proposed rule. This 3-year period will allow industry sufficient time to plan the acquisition and installation of this critical safety equipment. The following table summarizes the costs associated with this requirement.

Requirement	Total cost	Annual costs	Cost to small businesses
Proposed Rule—Install blind-shear rams within 1 year .....	\$14,000,000	\$14,000,000 over 1 year ....	\$0
Final Rule—Install blind-shear rams within 3 years .....	14,175,000	4,725,000 over 3 years .....	0

Avoidance of future blowout related costs, through the installation of blind-shear rams on all existing drilling rigs with surface BOP stacks, would constitute the potential benefits to lessees and their drilling contractors. In the analysis conducted for this rule, gross benefits are partially offset by the costs to purchase and install blind-shear rams, in surface BOP stacks that don't already have them. Our analysis indicates that implementation of the regulation will most likely result in net

present value benefits to lessees and drilling contractors of \$22 million. These benefits can be achieved by investing in the acquisition and installation of blind-shear rams for a present value cost of \$13 million. Accordingly, the present value of gross industry benefits from this regulation will most likely be \$35 million.

As discussed in the proposed rule, we believe that the final rule will not have a significant impact on small drilling contractors. It won't impact small

drilling contractors because there is only one that qualifies as a small business, and that contractor has already equipped its surface BOP stacks with blind-shear rams. The drilling contractor indicated that the blind-shear rams were installed as an additional safety precaution.

IADC also commented that MMS did not consider the consequences of the

inadvertent operation or malfunction of the blind-shear rams in the proposed rule. We know industry has many years of experience with having blind-shear rams in subsea BOP stacks and that industry has developed safeguards and procedures to prevent the inadvertent operation of this equipment. Also, several operators have many years of experience of having blind-shear rams in surface BOP stacks in the GOM. MMS, therefore, is confident that industry can adequately safeguard the BOP control panels and adequately train its personnel to prevent the inadvertent operation of blind-shear rams.

MMS disagrees with IADC's comment that the successful operation of blind-shear rams permanently forecloses other well control options. Many wells have been controlled after blind-shear rams shut them in. At least four of the wells identified in the table above regained control of the well by lubricating heavyweight drilling fluids into the annulus to kill the well (8/4/78; 10/5/81; 5/15/82; 3/20/87). While lubricating or bullheading fluids into a live well may not be the preferred method for regaining control of a well, it is better than losing total control of the well.

Finally, one commenter indicated that the operating limits of blind-shear rams are frequently unclear for some drilling operations due to pipe grades, mud weights, and wellbore pressures, and that consideration should be given to ensure that these limits are clear. We agree that this is important, so we have added a paragraph to § 250.416(e) that requires the lessee to address these issues. The new paragraph requires the lessee to provide information that shows that the blind-shear or shear rams installed in the BOP stack (both surface and subsea stacks) are capable of shearing the drill pipe in the hole under maximum anticipated surface pressures.

- *Comment on § 250.441 What are the requirements for a surface BOP stack?* MMS should revise the rule to allow an exception for less than four remote-controlled BOPs.

*Response:* Because you may include this request in your APD submission to the District Supervisor, we did not revise the rule to allow the use of less than four remote-controlled BOPs in certain situations.

- *Comment on § 250.442 What are the requirements for a subsea BOP stack?* One commenter asked why didn't MMS identify the costs associated with the subsea accumulator requirements.

*Response:* MMS did not specify any costs for this requirement because lessees/operators were already required by the regulations to have an accumulator that provided for fast

closure. API RP 53 now provides guidelines for determining the minimum requirements and performance for the subsea accumulator.

- *Comment on § 250.442 What are the requirements for a subsea BOP stack?* A commenter noted that section 13.3 of API RP 53 does not include subsea accumulator volume requirements that can be audited other than the specific response times.

*Response:* MMS will review BOP test records, including documentation of the closing times of ram and annular preventers, in evaluating BOP system performance.

- *Comment on § 250.443 What associated BOP systems and related equipment must my BOP system include?* MMS should clarify that this section applies to both surface and subsea BOP equipment. The commenter also recommended that MMS consider adopting more sections of API RP 53 and/or API RP 16E instead of having a number of the specific requirements stated in the BOP system sections (250.440 to 250.451). Adoption of these documents would provide a more rigorous standard than the current MMS requirements.

*Response:* We clarified the intent of this section by revising the title to read "What associated BOP systems and related equipment must my surface and subsurface BOP systems include?" MMS will consider incorporating additional sections of API RP 53 and API RP 16E or possibly the entire document in possible future revisions of the drilling regulations.

- *Comment on § 250.446 What must I do to maintain and inspect my BOP?* MMS should consider incorporating parts of other quality management standards into the regulations, such as API Q1's, "The supplier shall establish and maintain documented procedures for implementing corrective and preventive action \* \* \* and API Spec 16A's, Appendix G, "The operator of drill through equipment manufactured to this specification shall provide a written report to the equipment manufacturer of any malfunction or failure which occurs \* \* \*"

*Response:* The quality management program incorporated by sections 17.12 and 18.12 in API RP 53 pertains to a planned maintenance system for BOP equipment and to maintaining copies of equipment manufacturer's product alerts and bulletins. The purpose for incorporating these sections was to ensure that BOP equipment is maintained properly. It was not to require equipment specifications or certification requirements for BOP equipment. MMS believes that

incorporation of the specific sections of API RP 53 will meet the objective of identifying appropriate maintenance requirements.

- *Comment on § 250.448 What are the BOP pressure tests requirements?* MMS requirements for a low-pressure test provide a lower acceptance standard when compared to sections 17.3.2 and 18.3.2. MMS should consider incorporating these sections into the regulations.

*Response:* These sections of API RP 53 state the following on low-pressure tests: "When performing the low pressure test, do not apply a higher pressure and bleed down to the low test pressure. The higher pressure could initiate a seal that may continue to seal after the pressure is lowered and, therefore, misrepresenting a low pressure condition." MMS recognizes that this situation could occur on a low-pressure test, but we also recognize that it may be difficult to precisely apply 200 to 300 pounds per square inch (psi) to the component to be tested. Based on our experience and judgment, we have allowed operators to conduct a low-pressure test (200 to 300 psi) if the initial pressurization did not exceed 500 psi. Any pressure higher than 500 psi must be bled to zero and the test reinitiated.

- *Comment on § 250.448 What are the BOP pressure tests requirements?* MMS should consider testing ram preventers at an intermediate pressure, which ranges between 2,000 and 4,500 psi depending on closing ratio, because it provides a better measure of fitness for purpose. This intermediate pressure is another possible mode of failure. These intermediate pressure tests would be conducted initially and on an annual basis.

*Response:* MMS is unlikely to require such a test until it becomes an accepted industry practice.

- *Comment on § 250.449 What additional BOP testing requirements must I comply with?* The requirement for variable bore rams (VBRs) to pressure test against all sizes of pipe may be more rigorous than the largest and smallest sizes as recommended by API RP 53 (sections 17.5.5 and 18.5.5).

*Response:* We have revised the requirement in § 250.449(f) to now require you to pressure test VBRs against the largest and smallest sizes of pipe in use, excluding drill collars and bottom-hole tools. This conforms to API RP 53 recommended practice. Also, one of the findings from a 1999 research project, "Reliability of Subsea BOP Systems for Deepwater Application, Phase II DW, by Per Holand of SINTEF Industrial Management," recommended

that we should not require testing VBRs on all sizes. The rationale was that the testing of VBRs on all sizes adds very little to increased safety availability in the BOP due to the redundancy in the stack, and that most failures will occur during the pressure test.

• *Comment on § 250.449 What additional BOP testing requirements must I comply with?* Mandatory pressure testing of the BOP system after landing is not justified considering the extremely low failure rate of BOP components and the fact that the physical act of running the stack imposes little to no stress on the functional components of the BOP system. After a successful stump test, MMS should require only a function test for the BOP stack once it is on bottom. Function testing after landing will ensure that all control circuits are operating properly. This minor revision has a potentially huge beneficial impact by saving lost rig time to the initial BOP pressure test.

*Response:* We did not revise this requirement as suggested. We believe that the initial pressure test of the BOP stack after landing on the well is critical to ensuring that it functions properly. The results from our 1999 research project on the reliability of deep water subsea BOP systems (Holand, 1999) support our belief. That research project examined data from 83 wells that were drilled using subsea BOP stacks in the deep water GOM. The majority of the wells were spudded during July 1, 1997, to May 1, 1998. The results showed that 15 components failed during the initial pressure tests after the BOP stack landed on the wellhead. Of those 15 failures, 10 were in the control systems and may have been discovered in a function test. However, five other failures occurred (two connectors, one annular preventer, one ram preventer, one choke and kill valve) that may not have been discovered without the initial pressure test. MMS will continue to require the initial pressure test after landing the subsea BOP stack.

• *Comment on § 250.456 What are the required safe drilling fluid program practices?* Paragraph (a) should not require circulating the well before starting out of the hole if you have lost circulation.

*Response:* MMS believes that pipe should not be pulled out of the hole until a loss circulation pill has been spotted and the well is under control. It

is recommended that the top part of the hole be circulated to ensure that the wellbore is clear of gas. Some loss of returns is acceptable while pulling out of the hole; however, excessive loss circulation would require remaining on bottom until the loss was controlled either with a pill or cement.

• *Comment on § 250.456 What are the required safe drilling fluid program practices?* Recommend that MMS eliminate the second sentence in paragraph (e) which says "You must circulate and condition the well, on or near-bottom, unless well or drilling-fluid conditions prevent running the drill pipe back to the bottom." The first sentence of this requirement which says you must take appropriate measures to control the well is sufficient to address this situation.

*Response:* We did not remove the second sentence of this paragraph because this is a safe drilling practice. However, the sentence in question does allow for not running drill pipe to bottom to circulate the well if conditions prevent it.

• *Comment on § 250.456 What are the required safe drilling fluid program practices?* Recommend that paragraph (f) allow the District Supervisor the discretion to not require the posting of the surface pressure at which the shoe would break down.

*Response:* We did not revise this paragraph. You may request a departure from this requirement in your APD submission to the District Supervisor.

• *Comment on § 250.456 What are the required safe drilling fluid program practices?* MMS should allow the District Supervisor the discretion to not require degassers in all situations (paragraph (g)).

*Response:* We did not revise this paragraph. You may request a departure from this requirement in your APD submission to the District Supervisor.

• *Comment on § 250.458 What quantities of drilling fluids are required?* The commenter prefers the current wording over the proposed wording.

*Response:* The new regulations use a more active style of writing versus the passive style used in the previous regulations. The requirements (and most of the words) are the same.

• *Comments on § 250.459 What are the safety requirements for drilling-fluid-handling areas?* The two drilling contractors and IADC commented that the requirement to classify drilling-

fluid-handling areas according to API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, is in conflict with the 1998 MMS/USCG MOU as it relates to MODUs. The MOU assigns regulatory oversight of this subject matter to the USCG. USCG regulations at 46 CFR 108.170 and 108.187 clearly address these matters, as do the Classification Society requirements applicable to MODUs. Accordingly, the requirements in this section should not apply to MODUs.

*Response:* This is not a new requirement. The USCG is responsible for the inspection on this area for electrical requirements; it is classified due to a possible source for gas coming out of the cuttings. MMS inspects for gas detectors and tests them on a regular basis. If we see anything that does not meet the USCG's requirement, such as an exposed wire, then MMS would shut down operation and require that it be repaired. All drilling-fluid-handling areas are treated the same.

• *Comment on § 250.460 What are the requirements for well testing?* These requirements should not apply if a well test is conducted on a permanent production facility.

*Response:* Your projected plans for a well test on a permanent production facility must address all appropriate requirements. You may reference another document or plan if it addresses a specific requirement, such as the description of safety equipment.

• *Comment on § 250.465 When must I submit sundry notices to MMS?* An open hole sidetrack to go around junk in the hole and to continue drilling to the original approved APD should not require a sundry notice.

*Response:* All sidetracks require the submittal of a sundry notice, and the API number is incremented. This allows the logs to be tracked and handled correctly.

### III. OOC Comments on Specific Sections

The following table contains the OOC's unedited comments on the proposed requirements for oil and gas drilling operations and our response to those comments. In this table, we have italicized words that OOC wanted added to the regulations and have bracketed words that the OOC wanted deleted from the regulations.

Proposed section	OOO comments	OOO rationale	MMS response
250.198 .....	Incorporate correct editions of API RP 500 and API RP 505 into the regulations.	By FEDERAL REGISTER Notice dated January 4, 2000, MMS incorporated by reference API RP 500, Second Edition and API RP 505, First Edition. Proposed Rule should be modified to state such.	The final rule references the correct documents and editions.
250.401(b) .....	(b) Have a person onsite <i>24 hours per day during operations</i> that represents your interests and can fulfill your responsibilities.	Include 24 hours a day to provide clarity.	We did not add the 24 hours per day because it is unnecessary, but we did add during operations as suggested.
250.401(c) .....	(c) Ensure that the toolpusher or a member of the drilling crew maintains continuous surveillance of the rig floor from the beginning of drilling operations until the well is abandoned <i>or completed</i> , unless you have secured the well with blowout preventers (BOPs), <i>bridge plugs, cement plugs</i> , or packers.	Well may go from drilling to completion and not be abandoned. Additionally, bridge plugs and cement plugs are viable options for securing the well.	We made the suggested changes.
250.402 .....	When and how must I secure a well? Whenever you interrupt <i>drilling</i> operations, you must install a downhole safety device, such as a cement plug, bridge plug, or packer. You must install the the device [as deep as possible] <i>at an appropriate depth</i> within a properly cemented casing string <i>or liner</i> .	The use of the phrase "as deep as possible" infers that the device should be set at the bottom of the hole. By changing "as deep as possible" to "an appropriate depth" allows the operator flexibility to choose appropriate setting depths.	We made the suggested changes.
250.402(a) .....	(a) [Among] The events that may cause you to [interrupt] <i>temporarily suspend drilling operations or</i> .	The proposed text regarding what types of events require securing of well downhole is vague and open-ended. Therefore, we recommend the word "among" in paragraph (a) be deleted, and the remainder of the paragraph be amended as recommended to detail the specific type of events, which is consistent with existing requirements.	We did not make the suggested change because there may be other events that cause you to interrupt drilling operations. The wording as suggested would limit the events that would require the installation of a downhole safety device.
250.403(c) .....	Requested clarity for paragraph (c) When you move a drilling rig or related equipment on a platform. You must shut in each well below the surface and at the wellhead, unless otherwise approved by the District Supervisor.	The language proposed is very vague. It appears that a subsurface shut-in is only required to move a rig while located on a platform ( <i>i.e.</i> from well to well) and does not address rigging-up and rigging-down. Also applicability to MODUs is unclear (movement of cantilever jack-ups and floaters).	We revised the wording to clearly state when you must shut in each well below the surface and at the wellhead. The final wording is contained in § 250.406.
250.410(b)(3) .....	Form MMS-123S may require modifications to include additional information requirements. OOC requests that it be allowed to review and provide comments to the MMS, if the form is modified.	We assume that Form MMS-123S will be modified to contain new information requirements. Therefore, we believe it would be beneficial to both industry and the MMS to allow OOC to review the new form.	As previously discussed, MMS revised this form and the other subpart D drilling and well forms through a separate process. We provided an opportunity to comment on the revised forms and note that OOC did comment.
250.413(h) .....	(h) delete .....	We recommend that Line (h) be deleted. It is not clear how is this additional summary is to be submitted. ( <i>i.e.</i> Is it to be included in Form MMS 123S or is it a narrative summary to part of the ADP, or is it a separate submittal?) The language as proposed is unclear, and OOC is not sure of the intent, or the purpose of this additional reporting requirement. Additionally, the summary report of the shallow hazards site survey will have been previously submitted with the EP/DOCD under which the well will be drilled.	The revised paragraph (h) now says that your well drilling design criteria must include a summary report of the shallow hazards site survey if it was not previously submitted.



Proposed section	OOO comments	OOO rationale	MMS response
250.414 (a), (b), (d), (e), (f) and (g).	Clarity is requested for lines (a), (b), (d), (e), (f) and (g)—What items must my drilling prognosis include? (a) Projected plans for coring at specified depths; (b) Projected plans for logging; (d) Estimated depths to the top of significant marker formations; (e) Estimated depths to significant porous and permeable zones containing fresh water, oil, gas, or abnormally pressured formation fluids; (f) Estimated depths to <i>major</i> faults; and (g) Estimated depths of permafrost, if applicable.	Currently the majority this of data is captured in the APD Information Spreadsheet. However, will the proposed form MMS-123S include other required data, such as estimated depths to the top of significant marker formations, major faults, etc? OOO assumes that the intent of the requirement is to identify faults that can potentially lead to problems while drilling. Therefore, it is recommended that the language be modified to include major faults only.	With the exception of providing the estimated depths to faults, these requirements were contained in § 250.415(f)(5) of the current regulations. You may use form MMS-123S to provide as much of this information as appropriate. Information you do not include on that form must be included with the drilling prognosis. As for estimating the depths to faults, we made the suggested change to require only the estimated depths to major faults.
250.415(a) .....	Hole sizes and casing sizes, including: weights; grades; [tension] collapse, and burst values; types of connection; and setting depths (measured and TVD).	The requirement for including the tension value has been deleted from the proposed language. This information has not been required in the past. The need to now require this information is unclear. If this requirement remains, will the ADP Information Spreadsheet/form MMS-123S, be revised to capture these values?	We made this suggested change. We will continue to require the tension casing design safety factor which is covered in paragraph (b).
250.417(a) .....	(a) If sufficient environmental information and data are not available, the District Supervisor may require you to collect and report this information <i>during the period of operation. The information to be collected and reported will be related to the structural integrity of the drilling unit and the safe conduct of operations.</i>	Clarity. The proposed language is too broad and does not present under which conditions the additional data would be required.	We added the phrase “during operations” to the requirement as suggested. We did not add the second sentence because it is unnecessary. The context of the section sets the limits for the type of information to be collected.
250.417(b) .....	(b) The District Supervisor may require you to conduct additional surveys and soil borings before approving the APD, <i>if the District Supervisor cannot make a determination that the proposed drilling unit can be supported at the specific site.</i>	Clarity. The proposed language is too broad and does not present under which conditions the additional data would be required.	The sentence was revised as follows: The District Supervisor may require you to conduct additional surveys and soil borings before approving the APD if additional information is needed to make a determination that the conditions are capable of supporting the drilling unit.
250.420(b)(1) .....	(b) Casing Requirements. (1) You must design casing (including liners) to withstand the anticipated stresses imposed by tensile, compressive, and buckling loads; burst and collapse pressures; thermal effects; and combinations thereof].	OOO recommends that the phrase “and combinations thereof” be deleted because this statement is vague as to what combinations must be considered.	We did not make the suggested change. This is not a new requirement (currently in § 250.404(a)(3)). You must design casing to withstand all combinations.
250.420(b)(2) .....	(2) The casing design must include safety measures that ensure well control during drilling [and safe operations during the life of the well].	OOO recommends that the phrase “and safe operations during the life of the well” be deleted because it is too broad.	We did not make the suggested change. You must design your casing for the life of the well.
250.421(b) .....	(b) Use enough cement to fill the annular space back to the mud line. Verify annular fill by observing cement returns. If you cannot observe cement returns, use additional cement to ensure fill back to the mud line. <i>Excess cement may be washed out from the annulus below the mud line to a sufficient depth as necessary to facilitate well abandonment operations.</i> For drilling * * *	Cement in the annular area between the conductor and the drive/structural pipe can cause difficulty in cutting pipe and clearing the location below the mud line.	We did not make this suggested change. Washing out or displacing cement is covered by § 250.418(g). That paragraph now says that washing out cement must be addressed in the APD.

Proposed section	OOC comments	OOC rationale	MMS response
250.421(f) .....	If you use a liner as conductor or surface casing, you must set the top of the liner at least 200 feet above the previous casing/liner shoe. If you use a liner as an intermediate or production casing, you must set the top of the liner at least 100 feet above the previous casing shoe, <i>unless otherwise approved by the District Supervisor.</i>	It is common practice to achieve the liner-lap lengths discussed herein. However, there are instances when this is undesirable and, in those cases, a liner top packer is typically installed to ensure a good seal. The recommended language change will provide the District Supervisor the flexibility to approve a shorter liner-lap.	We did not make the suggested change of adding "unless otherwise approved by the District Supervisor." In fact, we have removed that phrase from many sections because it is unnecessary. The District Supervisor has the flexibility to approve many requests without that phrase in the regulations. To emphasize this flexibility, we have added to the drilling regulations two sections: § 250.408, "May I use alternative procedures or equipment during drilling operations?", and § 250.409, "May I obtain departures from these drilling requirements?"
250.421(f) .....	* * * If you use a liner as an intermediate or production casing, you must set the top of the liner at least 100 feet above the previous casing shoe.	Existing regulations include language that prohibits the use of a production liner when landed in a surface casing. Is this no longer the case?.	We have revised this paragraph to read "If you use a liner as an intermediate string below a surface string or production casing below an intermediate string, you must set the top of the liner at least 100 feet above the previous casing shoe." MMS does not allow production liner to be set inside the surface casing, thereby to be used for production except in very limited conditions. Each such liner set departure must be individually reviewed.
250.422(b) .....	When may I resume drilling after cementing? * * * (b) If you plan to nipple down your diverter or BOP stack during the 8- or 12-hour waiting time, you must determine, [in advance] when it will be safe to conduct this activity. Your determination must be <i>based on a knowledge of formations conditions encountered, presence of potential drilling hazards, actual well conditions while drilling, cementing and post cementing as well as past experience.</i>	The term "in advance" in the proposed text is very vague. We recommend it be removed and the actual information necessary to make the determination be stated. However, we do agree that the performance-based language as written in § 250.422(b) is appropriate. That is, making the operator responsible for assessing when it is safe to nipple down well control equipment. As a prudent operator, this assessment is made based on a knowledge of formations conditions encountered, presence of potential drilling hazards, actual well conditions while drilling, cementing and post cementing as well as past experience.	We made the following changes to this requirement: We replaced the phrase "in advance" with "before nipping down" because we wanted to ensure that no one made the determination after nipping down. We revised the last sentence of the requirement to include most of the wording suggested.
250.423(b) .....	(b) Change casing setting depths more than 100 feet TVD from the approved APD.	It is recommended that approval be obtained if the casing depth change is more than 100 feet TVD, not measured depth. Additionally, if the casing becomes stuck while running or other hole conditions prevent the running of casing to the projected setting depth, the operator should be allowed to cement the casing without seeking approval, and notify the District Supervisor subsequently.	We changed this paragraph to allow an increase of casing setting depth of up to 100 feet total vertical depth before requiring a submittal to the District Supervisor. In the case where the casing setting depth fell short of the planned depth, you would have to contact the District Supervisor only if the well conditions warranted revising your casing design (see § 250.423(a)).
250.423(h) .....	Submit geologic data and information to the District Supervisor that demonstrates the absence of shallow hydrocarbons or hazards. This information must include logging, [and] drilling fluid-monitoring <i>and other available geologic data</i> from wells previously drilled [within 500 feet] <i>in the immediate vicinity</i> of the proposed well path down to the next casing point.	The 500-foot limit is too prescriptive. This waiver should be based on the geologic data from an applicable analogous well.	We did not make the suggested change. The 500-foot distance was selected by MMS geologists and drilling engineers as a reasonable distance. MMS can best serve the industry by keeping the 500-foot distance in the regulations (see § 250.428(g)).

Proposed section	OOO comments	OOO rationale	MMS response
250.424(a) .....	(a) You must pressure test each string of casing to 70 percent of its minimum internal yield <i>or as otherwise approved by the District Supervisor</i> . This testing requirement does not apply to drive or structural casing. When a diverter is installed on conductor casing, you must test the casing to a minimum of 200 psi. [The District Supervisor may approve or require other casing test pressures.]	There is more than one currently approved method for calculating casing test pressure. We recommend that the alternative test methods be included in the new requirements, or allow the District Supervisor the discretion to approve alternative methods.	We chose not to list the alternative methods for calculating casing test pressure. You should address alternative test pressures or methods in your APD (see § 250.423).
250.431(a) .....	(a) Use diverter spool outlets and diverter lines that have [an internal diameter] <i>a nominal diameter</i> of at least 10 inches for surface wellhead configurations and at least 12 inches for floating drilling operations.	API line pipe is normally used for diverter lines. Line pipe is different than casing. The nominal size of line pipe normally refers to the OD (for larger sizes).	We made the suggested changes.
250.434 .....	(f) After drilling is completed, [retain all the records listed in this section for 2 years at the facility, at the lessee's field office nearest to the facility, or at another location conveniently available to the District Supervisor.] <i>the lessee must retain all the records listed in this section for 2 years and make them available at the District Supervisor's request.</i>	To require the lessee to maintain detailed drilling records at the facility or at the nearest field location after drilling is completed is unreasonable, and places an unnecessary recordkeeping burden on the operator. We do maintain these records; however, they are typically maintained in a central record center. The need to maintain test results in the field after the drill operations are completed is unclear. Should the need to review these records arise, they can be supplied at that time.	We deleted paragraph (f) and moved the recordkeeping requirements to §§ 250.466 and 250.467. Section 250.466 requires you to keep drilling records onsite during drilling operations. After completion of drilling activities, you may keep all records at a location of your choice. A table in § 250.467 gives the time periods for keeping all records.
250.440 .....	You must design, install, maintain, test and use the BOP system and system components to ensure well control * * *.	Include test in the proposed text to be complete and consistent with the existing requirements.	We made the suggested change.
250.441(b) .....	(b) Delete .....	We strongly recommend that this requirement be eliminated. We have reviewed the description of the incidents used by the MMS to justify the proposed requirement to install blind-shear rams in all BOP stacks and disagree with the conclusion that they support the need to require the installation of blind-shear rams. Furthermore, a 13 $\frac{5}{8}$ inch blind-shear rams would cost the drilling contractor an estimated \$82,000 plus transportation and installation costs. The total estimated cost imposed by this requirement would be \$150,000 per stack.	MMS did not make the suggested change. See response to comments in the previous part of the preamble. As for the \$150,000 cost per stack cited by OOC, we have used a cost of \$175,000 in our evaluation of impacts.
250.442(b) .....	(b) You must install a subsea accumulator closing unit, <i>or equivalent systems</i> to provide fast closure of the BOP components and to operate all critical functions in case of a loss of the power fluid connection to the surface. The [subsea] accumulator must meet or exceed the provisions of Section 13.3, Accumulator Volumetric Capacity, in API RP 53, Recommended Practice for Blowout Prevention Equipment Systems for Drilling Wells. The District Supervisor may approve a suitable alternative method.	Many BOP stacks on floating drilling rigs currently in operation do not meet the proposed requirement to install a subsea accumulator. In lieu of subsea accumulators, the inclusion of redundant power/control lines provides the equivalent protection necessary. Therefore, we recommend the inclusion of the statement "or equivalent system" to the proposed language.	Our changes to this paragraph follow the suggested changes (see § 250.442(c)).

Proposed section	OOC comments	OOC rationale	MMS response
250.442(d) .....	(d) Before removing the marine drilling riser, you must displace the riser with seawater, <i>except in the case of an emergency riser disconnect</i> , You must* * *.	Drillships and semi submersible drilling rigs with automatic station keeping (ASK) systems may experience ASK failures at which time the well must be isolated with the BOP and the marine riser disconnection immediately to prevent damage to well, equipment, and rig. It is therefore impractical to displace the marine riser with seawater prior to an emergency riser disconnect.	We did not make this suggested change. MMS realizes that during an emergency you will not be able to displace the riser with seawater, but this specific case does not need to be addressed in the regulations (see § 250.442(e)).
250.447(b) .....	(b) Before 14 days have elapsed since your last BOP pressure test, you must begin to test your BOP system before midnight on the 14th day following the conclusion of the previous test. However, the District Supervisor may [require more frequent testing] <i>require the test to be performed before midnight on the 7th day following the conclusion of the previous test</i> , if conditions or BOP performance warrant; and	More frequent testing without a specified interval is too broad.	We did not make the suggested change. MMS sees no reason to set a fixed BOP testing interval for when the District Supervisor may require more frequent testing. MMS may choose a test interval between 7 and 14 days depending on conditions or performance. BOP performance that warrants testing at less than 7-day intervals would likely lead to shutting in the drilling unit until you fix the problems.
250.448(b) .....	(b) High Pressure tests for ram type * * * Clarity requested.	OOC recognizes and appreciates MMS efforts to allow for BOP high-pressure tests requirements to include either testing to rated working pressure, or to 500 psi above the maximum allowable Surface Pressure (MASP) for the applicable section of the hole. However, we recommend that the proposed rule include acceptable methods for calculating MASP, to provide clarity.	MMS will not publish a list of acceptable methods to calculate MASP in the regulations. We don't believe that it is appropriate to limit the number of acceptable methods nor do we believe that such a list would provide clarity.
250.448(c) .....	(c) High pressure test for annular-type BOPs. The high pressure test must equal 70 percent of the rated 70 percent of the rated working pressure of the equipment, <i>or as otherwise approved by the District Supervisor</i> .	Currently approved procedures for testing annular preventers allow for testing to a pressure less than 70% of the working pressure, such as testing to the MASP.	We changed the paragraph to read "The high pressure test must equal 70% of the rated working pressure of the equipment or to a pressure approved in your APD."
250.450(c) .....	(c) Document the sequential order of BOP and auxiliary equipment testing and the pressure and duration of each test. [For subsea BOP systems, you must also record the closing times for annular and ram preventers.] You may reference a BOP test plan if it is available at the facility.	The requirement to record closing times should be removed. This requirement is not a common practice. Furthermore, there is no requirement for maximum closing time of a BOP, and it is unclear how the measurement of closing time would be determined (is it from the time the button is pushed until the fluid flow stop, or the time it takes the ram to fully stroke?). We do not see the value added by recording this time. Either, a BOP stack functions properly or not.	Section 250.442(c) requires that "the accumulator system equipment must meet or exceed the provisions of Section 13.3, Accumulator Volumetric Capacity, in API RP 53." Section 13.3.5 in API RP 53 says "For subsea installations, the BOP control system should be capable of closing each ram BOP in 45 seconds or less. Closing should not exceed 60 seconds for annular BOPs." As discussed in the preamble of the proposed rule, we incorporated API RP 53 by reference so that both industry and MMS would have guidelines for determining the minimum requirements and performance standards for subsea accumulators and BOP systems. As for the measurement of closing times, the RP states that "the measurement of closing response time begins at pushing the button or turning the control valve handle to operate the function and ends when the BOP or valve is closed, effecting a seal. A BOP is considered closed when the regulated operating pressure has recovered to its nominal setting."

Proposed section	OOC comments	OOC rationale	MMS response
250.450(g) .....	(g) After drilling is completed, [retain all the records listed in this section for 2 years at the facility, at the lessee's field office nearest to the facility, or at another location conveniently available to the District Supervisor.] <i>the lessee must retain all the records listed in this section for 2 years and make them available at the District Supervisor's request.</i>	To require the lessee to maintain detailed drilling records at the facility or at the nearest field office nearest field location after drilling operations are completed is unreasonable, and places an unnecessary record-keeping burden on the operator. We do not maintain these records; however, they are typically maintained in a central record center. The need to maintain test results in the field after the drill operations are completed is unclear. Should the need to review these records arise, they can be supplied at that time.	We deleted paragraph (g) and moved the record-keeping requirements to §§ 250.466 and 250.467. See previous discussion on § 250.434.
250.457(a) .....	(a) You must have and maintain drilling fluid-testing equipment on the drilling rig at all times. You must test the drilling fluid, when circulating at least once each tour or more frequently if conditions warrant. You must perform the tests according to industry-accepted practices. Tests must include density, viscosity, and gel strength; hydrogenion concentration; filtration; and any other tests the District Supervisor requires <i>for monitoring and maintaining drilling fluid quality for safe operations, prevention of downhole equipment problems and for the detection of kicks.</i> You must record * * *.	There are many times on a rig when circulation does not occur during a tour, or longer, and testing twice per day (once each tour) has no added value. Therefore, we recommend that this be a requirement during circulation only. Furthermore, the proposed text is too broad in regards to what type and why might the District Supervisor require additional test. The recommended language is consistent with the existing requirements.	We agree with the comment and moved the paragraph to become § 250.456(i). The new paragraph says: "When circulating, you must test the drilling fluid at least once each tour or more frequently if conditions warrant. You tests must conform to industry-accepted practices and include density, viscosity, and gel and gel strength; hydrogenion concentration; filtration; and any other tests the District Supervisor requires for monitoring drilling fluid quality, prevention of downhole equipment problems and for kick detection. You must record . . . ."
250.460(a) .....	Clarity requested .....	The proposed language is confusing. The title of this section is "What are the requirements for well testing?" However, paragraph (a) discusses determining formation characteristics using formation fluid samples and logging. It seems appropriate to put this paragraph in a section titled "what type samples, survey and tests of the formation are required." Please refer to 30 CFR 250.401(e) in the existing regulations.	We agree with the comment that the two paragraphs don't fit under this title. We moved paragraph (a) to its own section (now § 250.407 "What tests must I conduct to determine reservoir characteristics?") under general requirements. We then re-titled this section "What are the requirements for conducting a well test?"
250.461(a) .....	(a) Survey requirements for a vertical well: (1) You must conduct inclination surveys on each vertical well and [digitally] record the results. Survey intervals may not exceed 1,000 feet during the normal course of drilling. (2) You must also conduct a directional survey that provides both inclination and azimuth, <i>and digitally record the results in electronic format:</i>	Digitally recording inclination surveys while drilling a vertical well is not necessary or practical. Inclination surveys are used as a process control check to ensure that the well remains near vertical. The subsequent surveys, which include both inclination and azimuth, can be digitally recorded in electronic format. The phrase "electronic format" has been add to clarify that the record should be stored electronically for submittal to MMS, not record as "fingers" on a paper copy.	We made the suggested changes.
250.461(e) .....	(e) If you drill within 500 feet of an adjacent lease, the Regional Supervisor may require you to furnish a copy of the well's directional survey to the affected leaseholder, <i>if the leaseholder has requested the survey.</i>	The adjacent leaseholder should request the survey.	We revised the paragraph by adding the following sentence: "This could occur when the adjoining leaseholder requests a copy of the survey for the protection of correlative rights."
250.462(d) .....	(d) MMS ordered drill. An MMS authorized representative. The MMS representative will consult with <i>your onsite representative</i> before requiring the drill.	Clarifies who will be consulted prior to conducting the drill.	We made the suggested change.

Proposed section	OOC comments	OOC rationale	MMS response
250.465(a)(1) .....	Receive written or oral approval from the District Supervisor before you begin the intended operation. If you get an oral approval, you must submit form MMS-124 [within 72 hours] <i>no later than the end of the 3rd business day following the oral approval.</i> In all cases, you must meet the additional requirements in paragraph (b) of this section.	With weekends and holidays, it is often difficult to meet the 72-hour limitation.	We made the suggested change.
250.466(g) .....	(g) All other information required by the District Supervisor <i>in order to evaluate resource evaluation, waste prevention, conservation of natural resources, protection of correlative rights, safety or protection of the environment.</i>	Proposed language is very broad. The recommended language clarifies under what circumstances will additional information be requested.	We made the suggested changes.
250.467 .....	Delete section .....	As written, this section appears to be for informational purposes, rather than a requirement. Furthermore, the proposed language is vague. Line (a) discusses an NTL; Line (b) Specifies requirements for GOMR, but is silent on requirements for other regions. Line (c) as written appears that this is not mandatory, but at the discretion of the District Supervisor, and Line (d) eliminates the prescriptive requirements for legible, exact copies of service company records.	We renumbered this section to 250.469. The purpose of this section is to inform you what records the District Supervisor may require you to submit. The paragraphs identify the following: (a) well records, (b) paleontological reports and states that the Regional Supervisor may issue a Notice to Lessees that prescribes the manner, time-frame, and format for submitting this information, and (c) service company reports. We moved the requirements to submit form MMS-133, Well Activity Report, and daily drilling reports to the mandatory §§250.468(b) and (c).
250.515 (b) and 250.615 (b).	Delete this requirement .....	Please refer to rationale previously discussed in Section 250.441 of this document.	MMS did not make the suggested change. See our response to comments for §250.441.

## Procedural Matters

### Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget (OMB) has designated this a significant rule for OMB review under Executive Order 12866.

(1) The rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The major purpose of this rule is the restructuring of the rule and simplifying the regulatory language. The restructuring and plain language revisions will not result in any economic effects to small or large entities. Some of the technical revisions will have a minor economic effect on lessees and drilling contractors.

Specifically, given the existing industry structure (*i.e.*, the number and size of affected regulated entities remain constant), MMS estimates the cost to implement the rule at \$1 million annually.

In addition to the annual costs, the rule requires the installation of blind-shear rams in surface BOP stacks that will result in a one-time cost of \$14,175,000. This rule allows a 3-year period for the installation of the new rams. The most significant benefits of preventing or minimizing some blowouts will be the reduced risk of injury or fatality to personnel and of environmental damage. Property damages (including lost productivity) resulting from blowouts will also be reduced by this final rule. Property and financial damages from a blowout or near blowout can range from minimal damage to a facility and the loss of a day's activity to the total loss of the drilling rig and production facility.

MMS believes that the installation of blind-shear rams in surface BOP stacks could prevent or minimize approximately one blowout every 2 years. This estimate comes from the 5 incidents that MMS identified where a blind-shear ram had helped or could have helped prevent or minimize a blowout over the past 10-year period (1992 to present). Considering that a single blowout could cause multiple

fatalities, injuries, and tens of millions of dollars in property damage and financial losses, MMS believes that the benefits of this requirement will more than offset the cost of this new requirement.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The rule does not affect how lessees or operators interact with other agencies. Nor does this rule affect how MMS will interact with other agencies.

(3) This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. The rule only addresses the regulatory requirements for obtaining permission to drill on the OCS and the safety of drilling operations.

(4) OMB has determined that this rule raises novel legal or policy issues. The rule has some new policy issues, such as requiring minimum BOP maintenance requirements. OMB has determined that these issues make this rule a significant rule as defined in Executive Order 12866.

*Regulatory Flexibility (RF) Act*

The Department of the Interior (DOI) certifies that this rule will not have a significant economic effect on a substantial number of small entities under the RF Act (5 U.S.C. 601 *et seq.*). This rule applies to all lessees and drilling contractors that operate on the OCS. Small lessees and drilling contractors that operate under this final rule would fall under the Small Business Administration's (SBA) North American Industry Classification System codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111

Drilling Oil and Gas Wells. Under these codes, SBA considers all companies with fewer than 500 employees to be a small business. Given the variability in the industry due to changes in the relative prices of oil and natural gas, the numbers of small entities affected by the rule may change over time. Based on data from 1998, we estimate that of the 130 lessees that explore for and produce oil and gas on the OCS, approximately 90 are small businesses (70 percent). We also estimate that 10 drilling contractors operate on the OCS, and none of those drilling contractors are classified as a small business. The number of drilling

contractors is based on current drilling activity on the OCS, and the size of each drilling contractor is based on research into company statistics.

Drilling requirement costs will be borne by the OCS lessees who explore for and produce oil and are dependent on the number of wells drilled. We estimate that the total annual cost of the new drilling requirements in this rule to be approximately \$670,000, as shown in the following table. The table also shows the estimated cost per well for the approximately 700 wells drilled annually on the OCS using a surface BOP stack.

## ESTIMATED COSTS OF ADDITIONAL DRILLING REQUIREMENTS

Cost	Cost per well	Total cost for 700 wells drilled annually
One hour per well additional evaluation time on cementing operations @ \$100 .....	\$100	\$70,000
One hour per well additional drilling rig rental @ \$850 .....	850	\$595,000
Annual reporting and paperwork burden—140 hours @ \$50 .....	10	\$7,000
Total .....	960	\$672,000

\*The annual reporting and paperwork burden for the entire subpart D, "Oil and Gas Drilling Operations" is 111,209 hours as indicated in the Paperwork Reduction Act of 1995 section of this preamble. However, the new burden added when the this rule was proposed is only 140 hours (§ 250.403–100 hours; § 250.460(b)–30 hours; and § 250.461(e)—10 hours).

As indicated in the table, the estimated cost per well is about \$1,000. Based on drilling data from 1999, we estimate that the 90 small businesses that explore for and produce oil and gas on the OCS drill about 300 of the 700 wells drilled annually on the OCS using a surface BOP stack. Thus, with the small businesses drilling an average of 3½ wells per year, the annual economic effect for each small business is about \$3,300, or about \$300,000 in total. The estimated additional cost of \$1,000 per well is quite small (about .02 percent) when compared to the \$5 million average cost of drilling a well. Based on this very low percentage of well cost, we believe that these revisions to the regulations will not have a significant economic effect on any small lessee.

The estimated economic effect of the requirement to use blind-shear rams on surface BOP stacks is the cost to purchase the rams. This requirement imposes no reporting or recordkeeping burden. This requirement primarily will affect drilling contractors operating

jackup and platform rigs on the OCS who will be required to purchase the rams. Using information from 2003, the cost for a set of 10,000 pounds per-square-inch rams and associated equipment is about \$105,000. Some sets of rams for lower-rated BOP stacks will cost less, while a few sets of rams will cost more for higher-rated BOP stacks, but the average cost will remain at about \$105,000.

In the proposed rule we estimated that drilling contractors would need to purchase a total of 80 blind-shear rams to meet the proposed requirements. We have revised that estimate to 135 sets of rams for reasons as discussed in our response to comments. At an average cost of about \$105,000, the economic impact will be \$14,175,000. The largest drilling contractor may need to purchase up to 40 sets of blind-shear rams, while one drilling contractor will not have to purchase any blind-shear rams because it has already installed blind-shear rams in all of its surface BOP stacks. When asked why, a

company executive responded that it was a prudent safety measure. A large contractor may get a minor reduction in the cost with a bulk purchase, but this reduction should not significantly affect the competition between large and small contractors because the unit costs will not vary much. Purchase of the rams to meet the proposed requirements will be an initial one-time cost. A blind-shear ram should last for 20 years if properly maintained.

The blind-shear ram requirement should not hinder the ability of lessees or contractors, including small businesses, to conduct business on the OCS. The final rule provides for a 3-year period after the effective date for drilling contractors to plan and purchase the rams and associated equipment. This will allow contractors sufficient time to obtain the equipment.

The following table summarizes the estimated economic effects associated with this final rule.

Requirement	Frequency	Total cost	Cost to small businesses
New drilling rules .....	Annual .....	\$672,000	\$300,000
Use of blind-shear rams .....	One-time .....	14,175,000	0
Total .....	.....	14,847,000	300,000

We do not believe that this rule will have a significant impact on the lessees and drilling contractors who explore for and produce oil and gas on the OCS, including those that are classified as small businesses.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small business about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of MMS, call 1-888-REG-FAIR (1-888-734-3247). You may comment to the Small Business Administration without fear of retaliation. Disciplinary action for retaliation by an MMS employee may include suspension or termination from employment with the Department of the Interior.

*Small Business Regulatory Enforcement Fairness Act (SBREFA)*

This rule is not a major rule under (5 U.S.C. 804(2)) the SBREFA. The rule:

(1) Does not have an annual effect on the economy of \$100 million or more. As described above, we estimate that the annual cost of the rule to be approximately \$672,000. The cost for the blind-shear rams will be \$14,175,000, which will be spread over a 3-year period. This cost will not cause an annual effect on the economy of \$100 million.

(2) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The minor increase in drilling costs will not change the way the oil and gas industry conducts business, nor will it affect regional oil and gas prices; therefore, it will not cause major cost increases for consumers, the oil and gas industry, or any Government agencies.

(3) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or ability of United States-based enterprises to compete with foreign-based enterprises. All lessees and drilling contractors, regardless of nationality, will have to comply with the requirements of this rule. So the rule will not affect competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

*Paperwork Reduction Act (PRA) of 1995*

We examined the proposed rule and these final regulations under section 3507(d) of the PRA. The proposed rulemaking added only a few new information collection requirements, which we submitted to OMB for approval as part of the proposed rulemaking process. There have been some changes to the numbering of sections requiring the collection of information in the final regulations, as well as some clarifications. However, the final regulations do not impose any additional information collection paperwork burden.

MMS regulations in 30 CFR 250, subpart A, at §§ 250.140, 250.141, and 250.142 allow respondents to request the use of "alternative procedures or equipment" and "departures" to operating requirements. However, our information collection submission to OMB (1010-0114) indicated that the burden for these requests is covered under the applicable operating requirement. To account for these non-specific possibilities, as MMS renews the various collections covering subparts of the part 250 regulations and the other 30 CFR parts, as a standard procedure we are now including these requests as a "line item" in the regulation burden charts. Based on comments we received on the proposed subpart D rulemaking, §§ 250.408 and 250.409 of these final regulations

specifically address these issues and a line item has been included in the burden chart for this collection. It should be reiterated that these requests are not new information collection requirements. However, this inclusion will ensure that the burden is not overlooked for some operating requirements and will provide for any oversight.

Because of the adjustments discussed in the preceding paragraphs and section numbering changes, before publication, we again submitted the final subpart D information collection to OMB and OMB approved them under OMB control number 1010-0141, with a current expiration date of January 28, 2003. An agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The title of the collection of information for this final rule is "30 CFR 250, Subpart D—Oil and Gas Drilling Operations." Respondents include approximately 130 Federal OCS oil and gas or sulphur lessees. The frequency of response varies, depending upon the requirement. Responses are mandatory. MMS will protect proprietary information according to the Freedom of Information Act and 30 CFR 250.196, "Data and information to be made available to the public."

The final regulations convert into plain language and restructure the requirements for oil and gas drilling operations. The approved information collection for this final rule will supersede the collection for current subpart D regulations (OMB control number 1010-0053), which we will cancel when the new subpart D regulations take effect.

We estimate the total annual paperwork "hour" burden for the final rule to be 111,209 hours. Following is a breakdown of the hour burden estimate.



Citation 30 CFR 250 Subpart D	Reporting and recordkeeping requirement	Hour burden	Average number per year	Annual burden hours
402(b) .....	Request approval to use blind or blind-shear ram or pipe rams and inside BOP.	.25	6 requests .....	2
403 .....	Notify MMS of drilling rig movement on or off drilling location .....	.1	20 notices .....	2
	In Gulf of Mexico OCS Region, rig movements reported on form MMS-144—burden covered under 1010-0150.			
408, 409 .....	Apply for use alternative procedures and/or departures not requested in MMS forms (including discussions with MMS and approvals.	1	20% of 1,200 drilling ops. = 240.	240
408, 409; 410-418, plus various other references in subpart D.	Apply for permit to drill and requests for various approvals required in subpart D (including §§ 250.423, 424, 442(c), 451(g), 456(f)) and obtained via forms MMS-123 (Application for Permit to Drill) and MMS-123S (Supplemental APD Information Sheet), and supporting information and notices to MMS—burden covered under 1010-0044 and 1010-0131.			0
410(a)(3), 417(b) .....	Reference to Exploration Plan, Development and Production Plan, Development Operations Coordination Document (30 CFR 250, subpart B)—burden covered under 1010-0049.			0
417(a), (b) .....	Collect and report additional information on case-by-case basis if sufficient information is not available.	4	1 report .....	4
417(c) .....	Submit 3rd party review of drilling unit according to 30 CFR 250, subpart I—burden covered under 1010-0058.			0
418(e) .....	Submit welding and burning plan according to 30 CFR 250, subpart A—burden covered under 1010-0114			0
421; 423; 428 .....	Submit casing and cementing program and revisions or changes .....	2	20% of 1,200 drilling ops. = 240.	480
424 .....	Caliper, pressure test, or evaluate casing; submit evaluation results; request approval before resuming operations or beginning repairs (every 30 days during prolonged drilling).	5	20% of 1,200 wells = 240.	1,200
456(c), (f) .....	Perform various calculations; post information (on occasion, daily, weekly).	.25	144 drilling rigs × 52 = 7,488.	1,872
459(a)(3) .....	Request exception to procedure for protecting negative pressure area.	2	5 requests .....	10
460; 465 .....	Submit revised plans, changes, well/drilling records, etc., on forms MMS-124 (Application for Permit to Modify) or MMS-125 (End of Operations Report)—burden covered under 1010-0045 and 1010-0046			0
460 .....	Submit plans for well testing and notify MMS before test .....	2	15 plans .....	30
461(e) .....	Provide copy of well directional survey to affected leaseholder .....	1	10 occasions .....	10
462(a) .....	Prepare and post well control drill plan for crew members .....	3	26 plans .....	78
463(b) .....	Request field drilling rules be established, amended, or canceled .....	2.5	6 requests .....	15
468(a) .....	Submit well logs .....	1.5	1,200 logs/surveys .....	1,800
	Submit directional and vertical-well surveys .....	.5	1,200 reports .....	600
	Submit velocity profiles and surveys .....	.25	55 reports .....	14
	Submit core analyses .....	.25	150 analyses .....	38
468(b); 465(b)(3) .....	In the GOM OCS Region, submit drilling activity reports on form MMS-133 (Well Activity Report)—burden covered under 1010-0132			0
468(c) .....	In the Pacific and Alaska OCS Regions during drilling operations, submit daily drilling reports.	1	14 wells × 365 days × 20% = 1,022.	1,022
469 .....	As specified by region, submit well records, paleontological interpretations or reports, service company reports, and other reports or records of operations.	.25	300 submissions .....	75
490(c)(4), (d) .....	Submit request for reclassification of H <sub>2</sub> S zone; notify MMS if conditions change.	1.7	27 responses .....	46
490(f); also referred to in 418(d).	Submit contingency plans for operations in H <sub>2</sub> S areas (16 drilling, 5 work-over, 6 production).	10	27 plans .....	270
490(i) .....	Display warning signs—no burden as facilities would display warning signs and use other visual and audible systems.			0
490(j)(12) .....	Propose alternatives to minimize or eliminate SO <sub>2</sub> hazards—submitted with contingency plans—burden covered under 250.490(f).			0
490(j)(13)(vi) .....	Label breathing air bottles—no burden as supplier normally labels bottles; facilities would routinely label if not.			0
490(l) .....	Notify (phone) MMS of unplanned H <sub>2</sub> S releases (approx. 2/year) .....	.2	49 facilities × 2 = 98 .....	20
490(o)(5) .....	Request approval to use drill pipe for well testing .....	2	3 requests .....	6

Citation 30 CFR 250 Subpart D	Reporting and recordkeeping requirement	Hour burden	Average number per year	Annual burden hours
490(q)(1) .....	Seal and mark for the presence of H <sub>2</sub> S cores to be transported—no burden as facilities would routinely mark transported cores.			0
490(q)(9) .....	Request approval to use gas containing H <sub>2</sub> S for instrument gas .....	2	3 requests .....	6
490(q)(12) .....	Analyze produced water disposed of for H <sub>2</sub> S content and submit results to MMS on occasion (approx. weekly).	2.8	4 production platforms × 52 = 208.	582
Reporting Subtotal	.....	.....	12,590 Responses .....	8,422
404 .....	Perform operational check of crown block safety device; record results (weekly).	.1	144 drilling rigs × 52 = 7,488.	749
426 .....	Perform pressure test on all casing strings and drilling liner lap; record results.	2	144 drilling rigs × approx. 50 per rig = 7,200.	14,400
427(a) .....	Perform pressure-integrity tests and related hole-behavior observations; record results.	4	425 tests .....	1,700
434; 467 .....	Perform diverter tests when installed and once every 7 days; actuate system at least once every 24-hour period; record results (average 2 per drilling operation).	2	1,200 drilling ops. × 2 = 2,400.	4,800
450; 467 .....	Perform BOP pressure tests, actuations and inspections when installed; at a minimum every 14 days; as stated for components; record results.	6	144 drilling rigs × approx. 35 per rig = 5,040.	30,240
450, 467 .....	Function test annulars and rams; document results every 7 days between BOP tests (biweekly). Note: this test is part of BOP test when BOP test is conducted.	.16	144 drilling rigs × approx. 20 per rig = 2,880.	461
451(c) .....	Record reason for postponing BOP test (on occasion—approx. 2/ year).	.1	144 drilling rigs × 2 = 288.	29
456(b), (i); 458(b) .....	Record each drilling fluid circulation; test drilling fluid, record results; record daily inventory of drilling fluid/materials; test and recalibrate gas detectors; record results (on occasion, daily, weekly, quarterly).	1.25	144 drilling rigs × 52 = 7,488.	9,360
462(c) .....	Perform well-control drills; record results (2 crews weekly) .....	1	144 drilling rigs × 2 crews × 52 = 14,976.	14,976
466, 467 .....	Retain drilling records for 90 days after drilling is complete; retain casing/liner pressure, diverter, and BOP for 2 years; retain well completion/well workover until well is permanently plugged/abandoned or lease assigned.	1.5	Annual records maintenance for 1,200 wells.	1,800
490(g)(2), (g)(5) .....	Conduct H <sub>2</sub> S training; post safety instructions; document training on occasion and annual refresher (approx. 2/year).	2	49 facilities × 2 = 98 .....	196
490(h)(2) .....	Conduct weekly drills and safety meetings; document attendance .....	1	49 facilities × 52 = 2,548	2,548
490(j)(8) .....	Test H <sub>2</sub> S detection and monitoring sensors during drilling; record testing and calibrations on occasion, daily during drilling (approx. 12 sensors per rig).	2	26 drilling rigs × 365 days = 9,490.	18,980
490(j)(8) .....	Test H <sub>2</sub> S detection and monitoring sensors every 14 days during production; record testing and calibrations (approx. 30 sensors/5 platforms + approx. 42 sensors/23 platforms).	3.5	28 production platforms × 26 = 728.	2,548
Recordkeeping Subtotal.	.....	.....	130 Record-keepers .....	102,787
Total Hour Burden.	.....	.....	12,720 .....	111,209

*Federalism (Executive Order 13132)*

According to Executive Order 13132, this rule does not have Federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State Governments. The rule applies to lessees and drilling contractors that operate on the OCS. This rule does not impose costs on States or localities. Any costs will be the responsibility of the lessees and drilling contractors.

*Takings Implication Assessment (Executive Order 12630)*

According to Executive Order 12630, the rule does not have significant Takings Implications. A Takings Implication Assessment is not required. The rule revises existing operation regulations. It does not prevent any lessee, operator, or drilling contractor from performing operations on the OCS, provided they follow the regulations. Thus, MMS did not need to prepare a Takings Implication Assessment under Executive Order 12630, Governmental Actions and Interference with

*Constitutionally Protected Property Rights.**Energy Supply, Distribution, or Use (Executive Order 13211)*

Although OMB has designated this a significant rule under Executive Order 12866, it does not have a significant effect on energy supply, distribution, or use. The rule essentially clarifies the current regulatory requirements for oil and gas drilling on the OCS. The rule also adds a new requirement (blind-shear rams in surface BOP stacks) that will result in a one-time cost to the industry of \$14,175,000. However, the

increased safety aspects associated with the new requirement along with the potential for reduced property damages and financial losses will offset the \$14,175,000 cost of the new rams. Accordingly the new requirement will not cause a reduction in crude oil supply or an increase in energy prices.

*Civil Justice Reform (Executive Order 12988)*

According to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order.

*National Environmental Policy Act (NEPA)*

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental assessment is not required.

*Unfunded Mandates Reform Act (UMRA) of 1995 (Executive Order 12866)*

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have any Federal mandates, nor does the rule have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

**List of Subjects in 30 CFR Part 250**

Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Mineral royalties, Oil and gas development and production, Oil and gas exploration, Oil and gas reserves, Penalties, Pipelines, Public

lands-mineral resources, Public lands-rights-of-way, Reporting and recordkeeping requirements, Sulphur development and production, Sulphur exploration, Surety bonds.

Dated: October 24, 2002.

**Rebecca W. Watson,**

*Assistant Secretary, Land and Minerals Management.*

For the reasons stated in the preamble, the Minerals Management Service (MMS) amends 30 CFR Part 250 as follows:

**PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF**

1. The authority citation for part 250 continues to read as follows:

**Authority:** 43 U.S.C. 1331 *et seq.*

2. In § 250.102, in the table in paragraph (b), paragraph (1) is revised to read as follows:

For information about	Refer to
(1) Applications for permit to drill .....	§ 250.410
* * * * *	* * * * *

3. In § 250.105, in the definition for Facility (3), the citation “§ 250.417(b)” is revised to read “§ 250.490(b)”.

4. In § 250.198, in the table in paragraph (e), the following changes are made in alphanumeric order:

A. Add an entry for API RP 53 as set forth below.

B. Revise the entries for ANSI Z88.2–1992, API RP 500, API RP 505, and NACE Standard MR0175–99 as set forth below.

**250.198 Documents incorporated by reference.**

\* \* \* \* \*  
(e) \* \* \*

Title of documents	Incorporated by reference at
* * * * *	* * * * *
ANSI Z88.2–1992, American National Standard for Respiratory Protection .....	§ 250.490(g)(4)(iv), (j)(13)(ii).
* * * * *	* * * * *
API RP 53, Recommended Practices for Blowout Prevention Equipment Systems for Drilling Wells, Third Edition, March 1997, API Stock No. G53003.	§ 250.442(c); § 250.446(a).
API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class I, Division 1 and Division 2, Second Edition, November 1997, API Stock No. C50002.	§ 250.114(a); § 250.459; § 250.802(e)(4)(i); § 250.803(b)(9)(i); § 250.1628(b)(3); (d)(4)(i); § 250.1629(b)(4)(i).
API RP 505, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class I, Zone 0, Zone 1, and Zone 2, First Edition, November 1997, API Stock No. C50501.	§ 250.114(a); § 250.459; § 250.802(e)(4)(i); § 250.803(b)(9)(i); § 250.1628(b)(3); (d)(4)(i); § 250.1629(b)(4)(i).
* * * * *	* * * * *
NACE Standard MR0175–99, Sulfide Stress Cracking Resistant Metallic Materials for Oilfield Equipment, Revised January 1999, NACE Item No. 21302.	§ 250.490(p)(2).
* * * * *	* * * * *

5. In § 250.199, in the table in paragraph (e), the OMB control number “1010–0053” cited in the entry for item (4) is revised to read “1010–0141”.

6. In § 250.203, the following changes are made:

A. In paragraphs (b)(5)(i) and (b)(5)(ii), the citation “250.417” is revised to read “250.490”.

B. In paragraph (p), the citation “§ 250.414” is revised to read “§ 250.410 through § 250.418”.

7. In § 250.204, the following changes are made:

A. In paragraphs (b)(2)(i) and (b)(2)(ii), the citation “§ 250.417” is revised to read “§ 250.490”.

B. In paragraph (t), the citation “§ 250.414” is revised to read “§ 250.410 through § 250.418”.

8. In 30 CFR part 250, subpart D, § 250.417 is redesignated as § 250.490, §§ 250.400 through 250.416 are revised, and §§ 250.417 through 250.469 are added, and a new undesignated center heading is added preceding redesignated § 250.490 to read as set forth below. For the convenience of the reader, the table of contents for subpart D is also set forth below:

#### **Subpart D—Oil and Gas Drilling Operations**

##### **General Requirements**

###### *Sec.*

- 250.400 Who is subject to the requirements of this subpart?
- 250.401 What must I do to keep wells under control?
- 250.402 When and how must I secure a well?
- 250.403 What drilling unit movements must I report?
- 250.404 What are the requirements for the crown block?
- 250.405 What are the safety requirements for diesel engines used on a drilling rig?
- 250.406 What additional safety measures must I take when I conduct drilling operations on a platform that has producing wells or has other hydrocarbon flow?
- 250.407 What tests must I conduct to determine reservoir characteristics?
- 250.408 May I use alternative procedures or equipment during drilling operations?
- 250.409 May I obtain departures from these drilling requirements?

##### **Applying for a Permit To Drill**

- 250.410 How do I obtain approval to drill a well?
- 250.411 What information must I submit with my application?
- 250.412 What requirements must the location plat meet?
- 250.413 What must my description of well drilling design criteria address?
- 250.414 What must my drilling prognosis include?
- 250.415 What must my casing and cementing programs include?
- 250.416 What must I include in the diverter and BOP descriptions?
- 250.417 What must I provide if I plan to use a mobile offshore drilling unit (MODU)?
- 250.418 What additional information must I submit with my APD?

##### **Casing and Cementing Requirements**

- 250.420 What well casing and cementing requirements must I meet?
- 250.421 What are the casing and cementing requirements by type of casing string?
- 250.422 When may I resume drilling after cementing?
- 250.423 What are the requirements for pressure testing casing?
- 250.424 What are the requirements for prolonged drilling operations?
- 250.425 What are the requirements for pressure testing liners?

- 250.426 What are the recordkeeping requirements for casing and liner pressure tests?
- 250.427 What are the requirements for pressure integrity tests?
- 250.428 What must I do in certain cementing and casing situations?

##### **Diverter System Requirements**

- 250.430 When must I install a diverter system?
- 250.431 What are the diverter design and installation requirements?
- 250.432 How do I obtain a departure to diverter design and installation requirements?
- 250.433 What are the diverter actuation and testing requirements?
- 250.434 What are the recordkeeping requirements for diverter actuations and tests?

##### **Blowout Preventer (BOP) System Requirements**

- 250.440 What are the general requirements for BOP systems and system components?
- 250.441 What are the requirements for a surface BOP stack?
- 250.442 What are the requirements for a subsea BOP stack?
- 250.443 What associated systems and related equipment must all BOP systems include?
- 250.444 What are the choke manifold requirements?
- 250.445 What are the requirements for kelly valves, inside BOPs, and drill-string safety valves?
- 250.446 What are the BOP maintenance and inspection requirements?
- 250.447 When must I pressure test the BOP system?
- 250.448 What are the BOP pressure tests requirements?
- 250.449 What additional BOP testing requirements must I meet?
- 250.450 What are the recordkeeping requirements for BOP tests?
- 250.451 What must I do in certain situations involving BOP equipment or systems?

##### **Drilling Fluid Requirements**

- 250.455 What are the general requirements for a drilling fluid program?
- 250.456 What safe practices must the drilling fluid program follow?
- 250.457 What equipment is required to monitor drilling fluids?
- 250.458 What quantities of drilling fluids are required?
- 250.459 What are the safety requirements for drilling fluid-handling areas?

##### **Other Drilling Requirements**

- 250.460 What are the requirements for conducting a well test?
- 250.461 What are the requirements for directional and inclination surveys?
- 250.462 What are the requirements for well-control drills?
- 250.463 Who establishes field drilling rules?

##### **Applying for a Permit To Modify and Well Records**

- 250.465 When must I submit an Application for Permit to Modify (AMP) or an End of Operations Report to MMS?
- 250.466 What records must I keep?
- 250.467 How long must I keep records?
- 250.468 What well records am I required to submit?
- 250.469 What other well records could I be required to submit?

##### **Hydrogen Sulfide**

- 250.490 Hydrogen sulfide.

#### **Subpart D—Oil and Gas Drilling Operations**

##### **General Requirements**

###### **§ 250.400 Who is subject to the requirements of this subpart?**

The requirements of this subpart apply to lessees, operating rights owners, operators, and their contractors and subcontractors.

###### **§ 250.401 What must I do to keep wells under control?**

You must take necessary precautions to keep wells under control at all times. You must:

- (a) Use the best available and safest drilling technology to monitor and evaluate well conditions and to minimize the potential for the well to flow or kick;
- (b) Have a person onsite during drilling operations who represents your interests and can fulfill your responsibilities;
- (c) Ensure that the toolpusher, operator's representative, or a member of the drilling crew maintains continuous surveillance on the rig floor from the beginning of drilling operations until the well is completed or abandoned, unless you have secured the well with blowout preventers (BOPs), bridge plugs, cement plugs, or packers;
- (d) Use personnel trained according to the provisions of subpart O; and
- (e) Use and maintain equipment and materials necessary to ensure the safety and protection of personnel, equipment, natural resources, and the environment.

###### **§ 250.402 When and how must I secure a well?**

Whenever you interrupt drilling operations, you must install a downhole safety device, such as a cement plug, bridge plug, or packer. You must install the device at an appropriate depth within a properly cemented casing string or liner.

- (a) Among the events that may cause you to interrupt drilling operations are:
  - (1) Evacuation of the drilling crew;
  - (2) Inability to keep the drilling rig on location; or

(3) Repair to major drilling or well-control equipment.

(b) For floating drilling operations, the District Supervisor may approve the use of blind or blind-shear rams or pipe rams and an inside BOP if you don't have time to install a downhole safety device or if special circumstances occur.

**§ 250.403 What drilling unit movements must I report?**

(a) You must report the movement of all drilling units on and off drilling locations to the District Supervisor. This includes both MODU and platform rigs. You must inform the District Supervisor 24 hours before:

- (1) The arrival of an MODU on location;
- (2) The movement of a platform rig to a platform;
- (3) The movement of a platform rig to another slot;
- (4) The movement of an MODU to another slot; and
- (5) The departure of an MODU from the location.

(b) You must provide the District Supervisor with the rig name, lease number, well number, and expected time of arrival or departure.

(c) In the Gulf of Mexico OCS Region, you must report drilling unit movements on form MMS-144, Rig Movement Notification Report.

**§ 250.404 What are the requirements for the crown block?**

You must have a crown block safety device that prevents the traveling block from striking the crown block. You must check the device for proper operation at least once per week and after each drill-line slipping operation and record the results of this operational check in the driller's report.

**§ 250.405 What are the safety requirements for diesel engines used on a drilling rig?**

You must equip each diesel engine with an air take device to shut down the diesel engine in the event of a runaway.

(a) For a diesel engine that is not continuously manned, you must equip the engine with an automatic shutdown device;

(b) For a diesel engine that is continuously manned, you may equip

the engine with either an automatic or remote manual air intake shutdown device;

(c) You do not have to equip a diesel engine with an air intake device if it meets one of the following criteria:

- (1) Starts a larger engine;
- (2) Powers a firewater pump;
- (3) Powers an emergency generator;
- (4) Powers a BOP accumulator system;
- (5) Provides air supply to divers or confined entry personnel;
- (6) Powers temporary equipment on a nonproducing platform;
- (7) Powers an escape capsule; or
- (8) Powers a portable single-cylinder rig washer.

**§ 250.406 What additional safety measures must I take when I conduct drilling operations on a platform that has producing wells or has other hydrocarbon flow?**

You must take the following safety measures when you conduct drilling operations on a platform with producing wells or that has other hydrocarbon flow:

(a) You must install an emergency shutdown station near the driller's console;

(b) You must shut in all producible wells located in the affected wellbay below the surface and at the wellhead when:

(1) You move a drilling rig or related equipment on and off a platform. This includes rigging up and rigging down activities within 500 feet of the affected platform;

(2) You move or skid a drilling unit between wells on a platform;

(3) A mobile offshore drilling unit (MODU) moves within 500 feet of a platform. You may resume production once the MODU is in place, secured, and ready to begin drilling operations.

**§ 250.407 What tests must I conduct to determine reservoir characteristics?**

You must determine the presence, quantity, quality, and reservoir characteristics of oil, gas, sulphur, and water in the formations penetrated by logging, formation sampling, or well testing.

**§ 250.408 May I use alternative procedures or equipment during drilling operations?**

You may use alternative procedures or equipment during drilling operations

after receiving approval from the District Supervisor. You must identify and discuss your proposed alternative procedures or equipment in your Application for Permit to Drill (APD) (see § 250.414(h)). Procedures for obtaining approval are described in section 250.141 of this part.

**§ 250.409 May I obtain departures from these drilling requirements?**

The District Supervisor may approve departures from the drilling requirements specified in this subpart. You may apply for a departure from drilling requirements by writing to the District Supervisor. You should identify and discuss the departure you are requesting in your APD (see § 250.414(h)).

**Applying for a Permit To Drill**

**§ 250.410 How do I obtain approval to drill a well?**

You must obtain written approval from the District Supervisor before you begin drilling any well or before you sidetrack, bypass, or deepen a well. To obtain approval, you must:

(a) Submit the information required by § 250.411 through 250.418;

(b) Include the well in your approved Exploration Plan (EP), Development and Production Plan (DPP), or Development Operations Coordination Document (DOCD);

(c) Meet the oil spill financial responsibility requirements for offshore facilities as required by 30 CFR part 253; and

(d) Submit the following forms to the District Supervisor:

(1) An original and two complete copies of form MMS-123, Application for a Permit to Drill (APD), and form MMS-123S, Supplemental APD Information Sheet; and

(2) A separate public information copy of forms MMS-123 and MMS-123S that meets the requirements of § 250.127.

**§ 250.411 What information must I submit with my application?**

In addition to forms MMS-123 and MMS-123S, you must include the information described in the following table.

Information that you must include with an APD	Where to find a description
(a) Plat that shows locations of the proposed well .....	§ 250.412
(b) Design criteria used for the proposed well .....	§ 250.413
(c) Drilling prognosis .....	§ 250.414
(d) Casing and cementing programs .....	§ 250.415
(e) Diverter and BOP systems descriptions .....	§ 250.416
(f) Requirements for using an MODU .....	§ 250.417

Information that you must include with an APD	Where to find a description
(g) Additional information .....	§ 250.418

**§ 250.412 What requirements must the location plat meet?**

The location plat must:

- (a) Have a scale of 1:24,000 (1 inch = 2,000 feet);
- (b) Show the surface and subsurface locations of the proposed well and all the wells in the vicinity;
- (c) Show the surface and subsurface locations of the proposed well in feet or meters from the block line;
- (d) Contain the longitude and latitude coordinates, and either Universal Transverse Mercator grid-system coordinates or state plane coordinates in the Lambert or Transverse Mercator Projection system for the surface and subsurface locations of the proposed well; and
- (e) State the units and geodetic datum (including whether the datum is North American Datum 27 or 83) for these coordinates. If the datum was converted, you must state the method used for this conversion, since the various methods may produce different values.

**§ 250.413 What must my description of well drilling design criteria address?**

Your description of well drilling design criteria must address:

- (a) Pore pressures;
- (b) Formation fracture gradients, adjusted for water depth;
- (c) Potential lost circulation zones;
- (d) Drilling fluid weights;
- (e) Casing setting depths;
- (f) Maximum anticipated surface pressures. For this section, maximum anticipated surface pressures are the pressures that you reasonably expect to be exerted upon a casing string and its related wellhead equipment. In calculating maximum anticipated surface pressures, you must consider: drilling, completion, and producing conditions; drilling fluid densities to be used below various casing strings; fracture gradients of the exposed formations; casing setting depths; total well depth; formation fluid types; safety margins; and other pertinent conditions. You must include the calculations used to determine the pressures for the drilling and the completion phases, including the anticipated surface pressure used for designing the production string;
- (g) A single plot containing estimated pore pressures, formation fracture gradients, proposed drilling fluid weights, and casing setting depths in true vertical measurements;

- (h) A summary report of the shallow hazards site survey that describes the geological and manmade conditions if not previously submitted; and
- (i) Permafrost zones, if applicable.

**§ 250.414 What must my drilling prognosis include?**

Your drilling prognosis must include a brief description of the procedures you will follow in drilling the well. This prognosis includes but is not limited to the following:

- (a) Projected plans for coring at specified depths;
- (b) Projected plans for logging;
- (c) Planned safe drilling margin between proposed drilling fluid weights and estimated pore pressures. This safe drilling margin may be shown on the plot required by § 250.413(g);
- (d) Estimated depths to the top of significant marker formations;
- (e) Estimated depths to significant porous and permeable zones containing fresh water, oil, gas, or abnormally pressured formation fluids;
- (f) Estimated depths to major faults;
- (g) Estimated depths of permafrost, if applicable;
- (h) A list and description of all requests for using alternative procedures or departures from the requirements of this subpart in one place in the APD. You must explain how the alternative procedures afford an equal or greater degree of protection, safety, or performance, or why you need the departures; and
- (i) Projected plans for well testing (refer to § 250.460 for safety requirements).

**§ 250.415 What must my casing and cementing programs include?**

Your casing and cementing programs must include:

- (a) Hole sizes and casing sizes, including: weights; grades; collapse, and burst values; types of connection; and setting depths (measured and true vertical depth (TVD));
- (b) Casing design safety factors for tension, collapse, and burst with the assumptions made to arrive at these values;
- (c) Type and amount of cement (in cubic feet) planned for each casing string; and
- (d) In areas containing permafrost, setting depths for conductor and surface casing based on the anticipated depth of the permafrost. Your program must

provide protection from thaw subsidence and freezback effect, proper anchorage, and well control.

**§ 250.416 What must I include in the diverter and BOP descriptions?**

You must include in the diverter and BOP descriptions:

- (a) A description of the diverter system and its operating procedures;
- (b) A schematic drawing of the diverter system (plan and elevation views) that shows: (1) the size of the annular BOP installed in the diverter housing;
- (2) spool outlet internal diameter(s);
- (3) diverter-line lengths and diameters; burst strengths and radius of curvature at each turn; and
- (4) valve type, size, working pressure rating, and location;
- (c) A description of the BOP system and system components, including pressure ratings of BOP equipment and proposed BOP test pressures;
- (d) A schematic drawing of the BOP system that shows the inside diameter of the BOP stack, number and type of preventers, location of choke and kill lines, and associated valves; and
- (e) Information that shows the blind-shear rams installed in the BOP stack (both surface and subsea stacks) are capable of shearing the drill pipe in the hole under maximum anticipated surface pressures.

**§ 250.417 What must I provide if I plan to use a mobile offshore drilling unit (MODU)?**

If you plan to use a MODU, you must provide:

- (a) *Fitness requirements.* You must provide information and data to demonstrate the drilling unit's capability to perform at the proposed drilling location. This information must include the maximum environmental and operational conditions that the unit is designed to withstand, including the minimum air gap necessary for both hurricane and non-hurricane seasons. If sufficient environmental information and data are not available at the time you submit your APD, the District Supervisor may approve your APD but require you to collect and report this information during operations. Under this circumstance, the District Supervisor has the right to revoke the approval of the APD if information collected during operations show that the drilling unit is not capable of performing at the proposed location.

(b) *Foundation requirements.* You must provide information to show that site-specific soil and oceanographic conditions are capable of supporting the proposed drilling unit. If you provided sufficient site-specific information in your EP, DPP, or DOCD, you may reference that information. The District Supervisor may require you to conduct additional surveys and soil borings before approving the APD if additional information is needed to make a determination that the conditions are capable of supporting the drilling unit.

(c) *Frontier areas.* (1) If the design of the drilling unit you plan to use in a frontier area is unique or has not been proven for use in the proposed environment, the District Supervisor may require you to submit a third-party review of the unit's design. If required, you must obtain the third-party review according to § 250.903. You may submit this information before submitting an APD.

(2) If you plan to drill in a frontier area, you must have a contingency plan that addresses design and operating limitations of the drilling unit. Your plan must identify the actions necessary to maintain safety and prevent damage to the environment. Actions must include the suspension, curtailment, or modification of drilling or rig operations to remedy various operational or environmental situations (e.g. vessel motion, riser offset, anchor tensions, wind speed, wave height, currents, icing or ice-loading, settling, tilt or lateral movement, resupply capability).

(d) *U.S. Coast Guard (USCG) Documentation.* You must provide the current Certificate of Inspection or Letter of Compliance from the USCG. You must also provide current documentation of any operational limitations imposed by an appropriate classification society.

(e) *Floating drilling unit.* If you use a floating drilling unit, you must indicate that you have a contingency plan for moving off location in an emergency situation.

(f) *Inspection of unit.* The drilling unit must be available for inspection by the District Supervisor before commencing operations.

(g) Once the District Supervisor has approved a MODU for use, you do not need to re-submit the information required by this section for another APD to use the same MODU unless changes in equipment affect its rated capacity to operate in the District.

#### **§ 250.418 What additional information must I submit with my APD?**

You must include the following with the APD:

(a) Rated capacities of the drilling rig and major drilling equipment, if not already on file with the appropriate District office;

(b) A drilling fluids program that includes the minimum quantities of drilling fluids and drilling fluid materials, including weight materials, to be kept at the site;

(c) A proposed directional plot if the well is to be directionally drilled;

(d) A Hydrogen Sulfide Contingency Plan (see § 250.490), if applicable, and not previously submitted;

(e) A welding plan (see §§ 250.109 to 250.113) if not previously submitted;

(f) In areas subject to subfreezing conditions, evidence that the drilling equipment, BOP systems and components, diverter systems, and other associated equipment and materials are suitable for operating under such conditions;

(g) A request for approval if you plan to wash out or displace some cement to facilitate casing removal upon well abandonment; and

(h) Such other information as the District Supervisor may require.

#### **Casing and Cementing Requirements**

##### **§ 250.420 What well casing and cementing requirements must I meet?**

You must case and cement all wells. Your casing and cementing programs must meet the requirements of this section and of §§ 250.421 through 250.428.

(a) *Casing and cementing program requirements.* Your casing and cementing programs must:

(1) Properly control formation pressures and fluids;

(2) Prevent the direct or indirect release of fluids from any stratum through the wellbore into offshore waters;

(3) Prevent communication between separate hydrocarbon-bearing strata;

(4) Protect freshwater aquifers from contamination; and

(5) Support unconsolidated sediments.

(b) *Casing requirements.* (1) You must design casing (including liners) to withstand the anticipated stresses imposed by tensile, compressive, and buckling loads; burst and collapse pressures; thermal effects; and combinations thereof.

(2) The casing design must include safety measures that ensure well control during drilling and safe operations during the life of the well.

(c) *Cementing requirements.* You must design and conduct your cementing jobs so that cement composition, placement techniques, and waiting times ensure that the cement placed behind the bottom 500 feet of casing attains a minimum compressive strength of 500 psi before drilling out of the casing or before commencing completion operations.

##### **§ 250.421 What are the casing and cementing requirements by type of casing string?**

The table in this section identifies specific design, setting, and cementing requirements for casing strings and liners. For the purposes of subpart D, the casing strings in order of normal installation are as follows: drive or structural, conductor, surface, intermediate, and production casings (including liners). The District Supervisor may approve or prescribe other casing and cementing requirements where appropriate.

Casing type	Casing requirements	Cementing requirements
(a) Drive or Structural .....	Set by driving, jetting, or drilling to the minimum depth as approved or prescribed by the District Supervisor.	If you drilled a portion of this hole, you must use enough cement to fill the annular space back to the mudline.
(b) Conductor .....	Design casing and select setting depths based on relevant engineering and geologic factors. These factors include the presence or absence of hydrocarbons, potential hazards, and water depths. Set casing immediately before drilling into formations known to contain oil or gas. If you encounter oil or gas or unexpected formation pressure before the planned casing point, you must set casing immediately	Use enough cement to fill the calculated annular space back to the mudline. Verify annular fill by observing cement returns. If you cannot observe cement returns, use additional cement to ensure fill-back to the mudline. For drilling on an artificial island or when using a glory hole, you must discuss the cement fill level with the District Supervisor.

Casing type	Casing requirements	Cementing requirements
(c) Surface .....	Design casing and select setting depths based on relevant engineering and geologic factors. These factors include the presence or absence of hydrocarbons, potential hazards, and water depths.	Use enough cement to fill the calculated annular space to at least 200 feet inside the conductor casing. When geologic conditions such as near-surface fractures and faulting exist, you must use enough cement to fill the calculated annular space to the mudline.
(d) Intermediate .....	Design casing and select setting depth based on anticipated or encountered geologic characteristics or wellbore conditions.	Use enough cement to cover and isolate all hydrocarbon-bearing zones and isolate abnormal pressure intervals from normal pressure intervals in the well. As a minimum, you must cement the annular space 500 feet above the casing shoe and 500 feet above each zone to be isolated.
(e) Production .....	Design casing and select setting depth based on anticipated or encountered geologic characteristics or wellbore conditions.	Use enough cement to cover or isolate all hydrocarbon-bearing zones above the shoe. As a minimum, you must cement the annular space at least 500 feet above the casing shoe and 500 feet above the uppermost hydrocarbon-bearing zone.
(f) Liners .....	If you use a liner as conductor or surface casing, you must set the top of the liner at least 200 feet above the previous casing/liner shoe. If you use a liner as an intermediate string below a surface string or production casing below an intermediate string, you must set the top of the liner at least 100 feet above the previous casing shoe..	Same as cementing requirements for specific casing types. For example, a liner used as intermediate casing must be cemented according to the cementing requirements for intermediate casing.

**§ 250.422 When may I resume drilling after cementing?**

(a) After cementing surface, intermediate, or production casing (or liners), you may resume drilling after the cement has been held under pressure for 12 hours. For conductor casing, you may resume drilling after the cement has been held under pressure for 8 hours. One acceptable method of holding cement under pressure is to use float valves to hold the cement in place.

(b) If you plan to nipple down your diverter or BOP stack during the 8- or

12-hour waiting time, you must determine, before nipping down, when it will be safe to do so. You must base your determination on a knowledge of formation conditions, cement composition, effects of nipping down, presence of potential drilling hazards, well conditions during drilling, cementing, and post cementing, as well as past experience.

**§ 250.423 What are the requirements for pressure testing casing?**

The table in this section describes the minimum test pressures for each string

of casing. You may not resume drilling or other down-hole operations until you obtain a satisfactory pressure test. If the pressure declines more than 10 percent in a 30-minute test or if there is another indication of a leak, you must re-cement, repair the casing, or run additional casing to provide a proper seal. The District Supervisor may approve or require other casing test pressures.

Casing type	Minimum test pressure
(a) Drive or Structural .....	Not required
(b) Conductor .....	200 psi
(c) Surface, Intermediate, and Production .....	70 percent of its minimum internal yield

**§ 250.424 What are the requirements for prolonged drilling operations?**

If wellbore operations continue for more than 30 days within a casing string run to the surface:

(a) You must stop drilling operations as soon as practicable, and evaluate the effects of the prolonged operations on continued drilling operations and the life of the well. At a minimum, you must:

(1) Caliper or pressure test the casing; and

(2) Report the results of your evaluation to the District Supervisor and obtain approval of those results before resuming operations.

(b) If casing integrity has deteriorated to a level below minimum safety factors, you must:

(1) Repair the casing or run another casing string; and

(2) Obtain approval from the District Supervisor before you begin repairs.

**§ 250.425 What are the requirements for pressure testing liners?**

(a) You must test each drilling liner (and liner-lap) to a pressure at least equal to the anticipated pressure to which the liner will be subjected during the formation pressure-integrity test below that liner shoe, or subsequent liner shoes if set. The District

Supervisor may approve or require other liner test pressures.

(b) You must test each production liner (and liner-lap) to a minimum of 500 psi above the formation fracture pressure at the casing shoe into which the liner is lapped.

(c) You may not resume drilling or other down-hole operations until you obtain a satisfactory pressure test. If the pressure declines more than 10 percent in a 30-minute test or if there is another indication of a leak, you must re-cement, repair the liner, or run additional casing/liner to provide a proper seal.



**§ 250.426 What are the recordkeeping requirements for casing and liner pressure tests?**

You must record the time, date, and results of each pressure test in the driller's report maintained under standard industry practice. In addition, you must record each test on a pressure chart and have your onsite representative sign and date the test as being correct.

**§ 250.427 What are the requirements for pressure integrity tests?**

You must conduct a pressure integrity test below the surface casing or liner and all intermediate casings or liners. The District Supervisor may require you

to run a pressure-integrity test at the conductor casing shoe if warranted by local geologic conditions or the planned casing setting depth. You must conduct each pressure integrity test after drilling at least 10 feet but no more than 50 feet of new hole below the casing shoe. You must test to either the formation leak-off pressure or to an equivalent drilling fluid weight if identified in an approved APD.

(a) You must use the pressure integrity test and related hole-behavior observations, such as pore-pressure test results, gas-cut drilling fluid, and well kicks to adjust the drilling fluid program and the setting depth of the next casing string. You must record all test results

and hole-behavior observations made during the course of drilling related to formation integrity and pore pressure in the driller's report.

(b) While drilling, you must maintain the safe drilling margin identified in the approved APD. When you cannot maintain this safe margin, you must suspend drilling operations and remedy the situation.

**§ 250.428 What must I do in certain cementing and casing situations?**

The table in this section describes actions that lessees must take when certain situations occur during casing and cementing activities.

If you encounter the following situation:	Then you must . . .
(a) Have unexpected formation pressures or conditions that warrant revising your casing design.	Submit a revised casing program to the District Supervisor for approval.
(b) Need to increase casing setting depths more than 100 feet true vertical depth (TVD) from the approved APD due to conditions encountered during drilling operations.	Submit those changes to the District Supervisor for approval.
(c) Have indication of inadequate cement job (such as lost returns, cement channeling, or failure of equipment).	(1) Pressure test the casing shoe; (2) Run a temperature survey; (3) Run a cement bond log; or (4) Use a combination of these techniques.
(d) Inadequate cement job .....	Re-cement or take other remedial actions as approved by the District Supervisor.
(e) Primary cement job that did not isolate abnormal pressure intervals.	Isolate those intervals from normal pressures by squeeze cementing before you complete; suspend operations; or abandon the well, whichever occurs first.
(f) Decide to produce a well that was not originally contemplated for production.	Have at least two cemented casing strings (does not include liners) in the well. Note: All producing wells must have at least two cemented casing strings.
(g) Want to drill a well without setting conductor casing.	Submit geologic data and information to the District Supervisor that demonstrates the absence of shallow hydrocarbons or hazards. This information must include logging and drilling fluid-monitoring from wells previously drilled within 500 feet of the proposed well path down to the next casing point.
(h) Need to use less than required cement for the surface casing during floating drilling operations to provide protection from burst and collapse pressures.	Submit information to the District Supervisor that demonstrates the use of less cement is necessary.
(i) Cement across a permafrost zone .....	Use cement that sets before it freezes and has a low heat of hydration.
(j) Leave the annulus opposite a permafrost zone uncemented.	Fill the annulus with a liquid that has a freezing point below the minimum permafrost temperature and minimizes opposite a corrosion.

**Diverter System Requirements**

**§ 250.430 When must I install a diverter system?**

You must install a diverter system before you drill a conductor or surface hole. The diverter system consists of a diverter sealing element, diverter lines, and control systems. You must design, install, use, maintain, and test the diverter system to ensure proper diversion of gases, water, drilling fluid, and other materials away from facilities and personnel.

**§ 250.431 What are the diverter design and installation requirements?**

You must design and install your diverter system to:

(a) Use diverter spool outlets and diverter lines that have a nominal diameter of at least 10 inches for surface

wellhead configurations and at least 12 inches for floating drilling operations;

(b) Use dual diverter lines arranged to provide for downwind diversion capability;

(c) Use at least two diverter control stations. One station must be on the drilling floor. The other station must be in a readily accessible location away from the drilling floor;

(d) Use only remote-controlled valves in the diverter lines. All valves in the diverter system must be full-opening. You may not install manual or butterfly valves in any part of the diverter system;

(e) Minimize the number of turns (only one 90-degree turn allowed for each line for bottom-founded drilling units) in the diverter lines, maximize the radius of curvature of turns, and target all right angles and sharp turns;

(f) Anchor and support the entire diverter system to prevent whipping and vibration; and

(g) Protect all diverter-control instruments and lines from possible damage by thrown or falling objects.

**§ 250.432 How do I obtain a departure to diverter design and installation requirements?**

The table below describes possible departures from the diverter requirements and the conditions required for each departure. To obtain one of these departures, you must have discussed the departure in your APD and received approval from the District Supervisor.

If you want a departure to:	Then you must...
(a) Use flexible hose for diverter lines instead of rigid pipe. (b) Use only one spool outlet for your diverter system. (c) Use a spool with an outlet with an internal diameter of less than 10 inches on a surface wellhead. (d) Use a single diverter line for floating drilling operations on a dynamically positioned drillship.	Use flexible hose that has integral end couplings.  (1) Have branch lines that meet the minimum internal diameter requirements; and (2) Provide downwind diversion capability. Use a spool that has dual outlets with an internal diameter of at least 8 inches.  Maintain an appropriate vessel heading to provide for downwind diversion.

#### **§ 250.433 What are the diverter actuation and testing requirements?**

When you install the diverter system, you must actuate the diverter sealing element, diverter valves, and diverter-control systems and control stations. You must also flow-test the vent lines.

(a) For drilling operations with a surface wellhead configuration, you must actuate the diverter system at least once every 24-hour period after the initial test. After you have nipped up on conductor casing, you must pressure-test the diverter-sealing element and diverter valves to a minimum of 200 psi. While the diverter is installed, you must conduct subsequent pressure tests within 7 days after the previous test.

(b) For floating drilling operations with a subsea BOP stack, you must actuate the diverter system within 7 days after the previous actuation.

(c) You must alternate actuations and tests between control stations.

#### **§ 250.434 What are the recordkeeping requirements for diverter actuations and tests?**

You must record the time, date, and results of all diverter actuations and tests in the driller's report. In addition, you must:

- (a) Record the diverter pressure test on a pressure chart;
- (b) Require your onsite representative to sign and date the pressure test chart;
- (c) Identify the control station used during the test or actuation;
- (d) Identify problems or irregularities observed during the testing or actuations and record actions taken to remedy the problems or irregularities; and
- (e) Retain all pressure charts and reports pertaining to the diverter tests and actuations at the facility for the duration of drilling the well.

#### **Blowout Preventer (BOP) System Requirements**

#### **§ 250.440 What are the general requirements for BOP systems and system components?**

You must design, install, maintain, test, and use the BOP system and system components to ensure well control. The working-pressure rating of each BOP

component must exceed maximum anticipated surface pressures. The BOP system includes the BOP stack and associated BOP systems and equipment.

#### **§ 250.441 What are the requirements for a surface BOP stack?**

(a) When you drill with a surface BOP stack, you must install the BOP system before drilling below surface casing. The surface BOP stack must include at least four remote-controlled, hydraulically operated BOPs, consisting of an annular BOP, two BOPs equipped with pipe rams, and one BOP equipped with blind or blind-shear rams.

(b) No later than February 21, 2006, your surface BOP stack must include at least four remote-controlled, hydraulically operated BOPs consisting of an annular BOP, two BOPs equipped with pipe rams, and one BOP equipped with blind-shear rams. The blind-shear rams must be capable of shearing the drill pipe that is in the hole.

(c) You must install an accumulator system that provides 1.5 times the volume of fluid capacity necessary to close and hold closed all BOP components. The system must perform with a minimum pressure of 200 psi above the precharge pressure without assistance from a charging system. If you supply the accumulator regulators by rig air and do not have a secondary source of pneumatic supply, you must equip the regulators with manual overrides or other devices to ensure capability of hydraulic operations if rig air is lost.

(d) In addition to the stack and accumulator system, you must install the associated BOP systems and equipment required by the regulations in this subpart.

#### **§ 250.442 What are the requirements for a subsea BOP stack?**

(a) When you drill with a subsea BOP stack, you must install the BOP system before drilling below surface casing. The District Supervisor may require you to install a subsea BOP system before drilling below the conductor casing if proposed casing setting depths or local geology indicate the need.

(b) Your subsea BOP stack must include at least four remote-controlled, hydraulically operated BOPs consisting of an annular BOP, two BOPs equipped with pipe rams, and one BOP equipped with blind-shear rams.

(c) You must install an accumulator closing system to provide fast closure of the BOP components and to operate all critical functions in case of a loss of the power fluid connection to the surface. The accumulator system must meet or exceed the provisions of Section 13.3, Accumulator Volumetric Capacity, in API RP 53, Recommended Practices for Blowout Prevention Equipment Systems for Drilling Wells (incorporated by reference as specified in § 250.198). The District Supervisor may approve a suitable alternative method.

(d) The BOP system must include an operable dual-pod control system to ensure proper and independent operation of the BOP system.

(e) Before removing the marine riser, you must displace the riser with seawater. You must maintain sufficient hydrostatic pressure or take other suitable precautions to compensate for the reduction in pressure and to maintain a safe and controlled well condition.

#### **§ 250.443 What associated systems and related equipment must all BOP systems include?**

All BOP systems must include the following associated systems and related equipment:

(a) An automatic backup to the primary accumulator-charging system. The power source must be independent from the power source for the primary accumulator-charging system. The independent power source must possess sufficient capability to close and hold closed all BOP components.

(b) At least two BOP control stations. One station must be on the drilling floor. You must locate the other station in a readily accessible location away from the drilling floor.

(c) Side outlets on the BOP stack for separate kill and choke lines. If your stack does not have side outlets, you must install a drilling spool with side outlets.

(d) A choke and a kill line on the BOP stack. You must equip each line with two full-opening valves, one of which must be remote-controlled. For a subsea BOP system, both valves in each line must be remote-controlled. In addition:

(1) You must install the choke line above the bottom ram;

(2) You may install the kill line below the bottom ram; and

(3) For a surface BOP system, on the kill line you may install a check valve and a manual valve instead of the remote-controlled valve. To use this configuration, both manual valves must be readily accessible and you must install the check valve between the manual valves and the pump.

(e) A fill-up line above the uppermost BOP.

(f) Locking devices installed on the ram-type BOPs.

(g) A wellhead assembly with a rated working pressure that exceeds the maximum anticipated surface pressure.

#### **§ 250.444 What are the choke manifold requirements?**

(a) Your BOP system must include a choke manifold that is suitable for the anticipated surface pressures, anticipated methods of well control, the surrounding environment, and the corrosiveness, volume, and abrasiveness of drilling fluids and well fluids that you may encounter.

(b) Choke manifold components must have a rated working pressure at least as great as the rated working pressure of the ram BOPs. If your choke manifold has buffer tanks downstream of choke assemblies, you must install isolation valves on any bleed lines.

(c) Valves, pipes, flexible steel hoses, and other fittings upstream of the choke manifold must have a rated working pressure at least as great as the rated working pressure of the ram BOPs.

#### **§ 250.445 What are the requirements for kelly valves, inside BOPs, and drill-string safety valves?**

You must use or provide the following BOP equipment during drilling operations:

(a) A kelly valve installed below the swivel (upper kelly valve);

(b) A kelly valve installed at the bottom of the kelly (lower kelly valve). You must be able to strip the lower kelly valve through the BOP stack;

(c) If you drill with a mud motor and use drill pipe instead of a kelly, you must install one kelly valve above, and one strippable kelly valve below, the joint of drill pipe used in place of a kelly;

(d) On a top-drive system equipped with a remote-controlled valve, you

must install a strippable kelly-type valve below the remote-controlled valve;

(e) An inside BOP in the open position located on the rig floor. You must be able to install an inside BOP for each size connection in the drill string;

(f) A drill-string safety valve in the open position located on the rig floor. You must have a drill-string safety valve available for each size connection in the drill string;

(g) When running casing, you must have a safety valve in the open position available on the rig floor to fit the casing string being run in the hole;

(h) All required manual and remote-controlled kelly valves, drill-string safety valves, and comparable-type valves (*i.e.* kelly-type valve in a top-drive system) must be essentially full-opening; and

(i) The drilling crew must have ready access to a wrench to fit each manual valve.

#### **§ 250.446 What are the BOP maintenance and inspection requirements?**

(a) You must maintain your BOP system to ensure that the equipment functions properly. BOP maintenance must meet or exceed the provisions of Sections 17.10 and 18.10, Inspections; Sections 17.11 and 18.11, Maintenance; and Sections 17.12 and 18.12, Quality Management, described in API RP 53, Recommended Practices for Blowout Prevention Equipment Systems for Drilling Wells (incorporated by reference as specified in § 250.198).

(b) You must visually inspect your surface BOP system on a daily basis. You must visually inspect your subsea BOP system and marine riser at least once every 3 days if weather and sea conditions permit. You may use television cameras to inspect subsea equipment.

#### **§ 250.447 When must I pressure test the BOP system?**

You must pressure test your BOP system (this includes the choke manifold, kelly valves, inside BOP, and drill-string safety valve):

(a) When installed;

(b) Before 14 days have elapsed since your last BOP pressure test. You must begin to test your BOP system before midnight on the 14th day following the conclusion of the previous test. However, the District Supervisor may require more frequent testing if conditions or BOP performance warrant; and

(c) Before drilling out each string of casing or a liner. The District Supervisor may allow you to omit this test if you didn't remove the BOP stack to run the

casing string or liner and the required BOP test pressures for the next section of the hole are not greater than the test pressures for the previous BOP test. You must indicate in your APD which casing strings and liners meet these criteria.

#### **§ 250.448 What are the BOP pressure tests requirements?**

When you pressure test the BOP system, you must conduct a low-pressure and a high-pressure test for each BOP component. You must conduct the low-pressure test before the high-pressure test. Each individual pressure test must hold pressure long enough to demonstrate that the tested component(s) holds the required pressure. Required test pressures are as follows:

(a) *Low-pressure test.* All low-pressure tests must be between 200 and 300 psi. Any initial pressure above 300 psi must be bled back to a pressure between 200 and 300 psi before starting the test. If the initial pressure exceeds 500 psi, you must bleed back to zero and reinitiate the test.

(b) *High-pressure test for ram-type BOPs, the choke manifold, and other BOP components.* The high-pressure test must equal the rated working pressure of the equipment or be 500 psi greater than your calculated maximum anticipated surface pressure (MASP) for the applicable section of hole. Before you may test BOP equipment to the MASP plus 500 psi, the District Supervisor must have approved those test pressures in your APD.

(c) *High pressure test for annular-type BOPs.* The high pressure test must equal 70 percent of the rated working pressure of the equipment or to a pressure approved in your APD.

(d) *Duration of pressure test.* Each test must hold the required pressure for 5 minutes. However, for surface BOP systems and surface equipment of a subsea BOP system, a 3-minute test duration is acceptable if you record your test pressures on the outermost half of a 4-hour chart, on a 1-hour chart, or on a digital recorder. If the equipment does not hold the required pressure during a test, you must correct the problem and retest the affected component(s).

#### **§ 250.449 What additional BOP testing requirements must I meet?**

You must meet the following additional BOP testing requirements:

(a) Use water to test a surface BOP system;

(b) Stump test a subsea BOP system before installation. You must use water to conduct this test. You may use drilling fluids to conduct subsequent tests of a subsea BOP system;

(c) Alternate tests between control stations and pods;

(d) Pressure test the blind or blind-shear ram BOP during stump tests and at all casing points;

(e) The interval between any blind or blind-shear ram BOP pressure tests may not exceed 30 days;

(f) Pressure test variable bore-pipe ram BOPs against the largest and smallest sizes of pipe in use, excluding drill collars and bottom-hole tools;

(g) Pressure test affected BOP components following the disconnection or repair of any well-pressure containment seal in the wellhead or BOP stack assembly;

(h) Function test annular and ram BOPs every 7 days between pressure tests; and

(i) Actuate safety valves assembled with proper casing connections before running casing.

#### **§ 250.450 What are the recordkeeping requirements for BOP tests?**

You must record the time, date, and results of all pressure tests, actuations, and inspections of the BOP system, system components, and marine riser in the driller's report. In addition, you must:

(a) Record BOP test pressures on pressure charts;

(b) Require your onsite representative to sign and date BOP test charts and reports as correct;

(c) Document the sequential order of BOP and auxiliary equipment testing and the pressure and duration of each test. For subsea BOP systems, you must also record the closing times for annular and ram BOPs. You may reference a

BOP test plan if it is available at the facility;

(d) Identify the control station and pod used during the test;

(e) Identify any problems or irregularities observed during BOP system testing and record actions taken to remedy the problems or irregularities; and

(f) Retain all records, including pressure charts, driller's report, and referenced documents pertaining to BOP tests, actuations, and inspections at the facility for the duration of drilling.

#### **§ 250.451 What must I do in certain situations involving BOP equipment or systems?**

The table in this section describes actions that lessees must take when certain situations occur with BOP systems during drilling activities.

If you encounter the following situation:	Then you must . . .
(a) BOP equipment does not hold the required pressure during a test ... (b) Need to repair or replace a surface or subsea BOP system .....	Correct the problem and retest the affected equipment. First place the well in a safe, controlled condition (e.g., before drilling out a casing shoe or after setting a cement plug, bridge plug, or a packer).
(c) Need to postpone a BOP test due to well-control problems such as lost circulation, formation fluid influx, or stuck drill pipe. (d) BOP control station or pod that does not function properly ..... (e) Want to drill with a tapered drill-string .....	Record the reason for postponing the test in the driller's report and conduct the required BOP test on the first trip out of the hole. Suspend further drilling operations until that station or pod is operable. Install two or more sets of conventional or variable-bore pipe rams in the BOP stack to provide for the following: two sets of rams must be capable of sealing around the larger-size drill string and one set of pipe rams must be capable of sealing around the smaller-size drill string.
(f) Install casing rams in a BOP stack ..... (g) Want to use an annular BOP with a rated working pressure less than the anticipated surface pressure.	Test the ram bonnets before running casing. Demonstrate that your well control procedures or the anticipated well conditions will not place demands above its rated working pressure and obtain approval from the District Supervisor.
(h) Use a subsea BOP system in an ice-scour area .....	Install the BOP stack in a glory hole. The glory hole must be deep enough to ensure that the top of the stack is below the deepest probable ice-scour depth.

### **Drilling Fluid Requirements**

#### **§ 250.455 What are the general requirements for a drilling fluid program?**

You must design and implement your drilling fluid program to prevent the loss of well control. This program must address drilling fluid safe practices, testing and monitoring equipment, drilling fluid quantities, and drilling fluid-handling areas.

#### **§ 250.456 What safe practices must the drilling fluid program follow?**

Your drilling fluid program must include the following safe practices:

(a) Before starting out of the hole with drill pipe, you must properly condition the drilling fluid. You must circulate a volume of drilling fluid equal to the annular volume with the drill pipe just off-bottom. You may omit this practice if documentation in the driller's report shows:

(1) No indication of formation fluid influx before starting to pull the drill pipe from the hole;

(2) The weight of returning drilling fluid is within 0.2 pounds per gallon (1.5 pounds per cubic foot) of the drilling fluid entering the hole; and

(3) Other drilling fluid properties are within the limits established by the program approved in the APD.

(b) Record each time you circulate drilling fluid in the hole in the driller's report;

(c) When coming out of the hole with drill pipe, you must fill the annulus with drilling fluid before the hydrostatic pressure decreases by 75 psi, or every five stands of drill pipe, whichever gives a lower decrease in hydrostatic pressure. You must calculate the number of stands of drill pipe and drill collars that you may pull before you must fill the hole. You must also calculate the equivalent drilling fluid

volume needed to fill the hole. Both sets of numbers must be posted near the driller's station. You must use a mechanical, volumetric, or electronic device to measure the drilling fluid required to fill the hole;

(d) You must run and pull drill pipe and downhole tools at controlled rates so you do not swab or surge the well;

(e) When there is an indication of swabbing or influx of formation fluids, you must take appropriate measures to control the well. You must circulate and condition the well, on or near-bottom, unless well or drilling-fluid conditions prevent running the drill pipe back to the bottom;

(f) You must calculate and post near the driller's console the maximum pressures that you may safely contain under a shut-in BOP for each casing string. The pressures posted must consider the surface pressure at which the formation at the shoe would break

down, the rated working pressure of the BOP stack, and 70 percent of casing burst (or casing test as approved by the District Supervisor). As a minimum, you must post the following two pressures:

(1) The surface pressure at which the shoe would break down. This calculation must consider the current drilling fluid weight in the hole; and

(2) The lesser of the BOP's rated working pressure or 70 percent of casing-burst pressure (or casing test otherwise approved by the District Supervisor);

(g) You must install an operable drilling fluid-gas separator and degasser before you begin drilling operations. You must maintain this equipment throughout the drilling of the well;

(h) Before pulling drill-stem test tools from the hole, you must circulate or reverse-circulate the test fluids in the hole. If circulating out test fluids is not feasible, you may bullhead test fluids out of the drill-stem test string and tools with an appropriate kill weight fluid;

(i) When circulating, you must test the drilling fluid at least once each hour, or more frequently if conditions warrant. Your tests must conform to industry-accepted practices and include density, viscosity, and gel strength; hydrogenion concentration; filtration; and any other tests the District Supervisor requires for monitoring and maintaining drilling fluid quality, prevention of downhole equipment problems and for kick detection. You must record the results of these tests in the drilling fluid report; and

(j) In areas where permafrost and/or hydrate zones are present or may be present, you must control drilling fluid temperatures to drill safely through those zones.

#### **§ 250.457 What equipment is required to monitor drilling fluids?**

Once you establish drilling fluid returns, you must install and maintain the following drilling fluid-system monitoring equipment throughout subsequent drilling operations. This equipment must have the following indicators on the rig floor:

(a) Pit level indicator to determine drilling fluid-pit volume gains and losses. This indicator must include both a visual and an audible warning device;

(b) Volume measuring device to accurately determine drilling fluid volumes required to fill the hole on trips;

(c) Return indicator devices that indicate the relationship between drilling fluid-return flow rate and pump discharge rate. This indicator must include both a visual and an audible warning device; and

(d) Gas-detecting equipment to monitor the drilling fluid returns. The indicator may be located in the drilling fluid-logging compartment or on the rig floor. If the indicators are only in the logging compartment, you must continually man the equipment and have a means of immediate communication with the rig floor. If the indicators are on the rig floor only, you must install an audible alarm.

#### **§ 250.458 What quantities of drilling fluids are required?**

(a) You must use, maintain, and replenish quantities of drilling fluid and drilling fluid materials at the drill site as necessary to ensure well control. You must determine those quantities based on known or anticipated drilling conditions, rig storage capacity, weather conditions, and estimated time for delivery.

(b) You must record the daily inventories of drilling fluid and drilling fluid materials, including weight materials and additives in the drilling fluid report.

(c) If you do not have sufficient quantities of drilling fluid and drilling fluid material to maintain well control, you must suspend drilling operations.

#### **§ 250.459 What are the safety requirements for drilling fluid-handling areas?**

You must classify drilling fluid-handling areas according to API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class I, Division 1 and Division 2 (incorporated by reference as specified in § 250.198); or API RP 505, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class 1, Zone 0, Zone 1, and Zone 2 (incorporated by reference as specified in § 250.198). In areas where dangerous concentrations of combustible gas may accumulate, you must install and maintain a ventilation system and gas monitors. Drilling fluid-handling areas must have the following safety equipment:

(a) A ventilation system capable of replacing the air once every 5 minutes or 1.0 cubic feet of air-volume flow per minute, per square foot of area, whichever is greater. In addition:

(1) If natural means provide adequate ventilation, then a mechanical ventilation system is not necessary;

(2) If a mechanical system does not run continuously, then it must activate when gas detectors indicate the presence of 1 percent or more of combustible gas by volume; and

(3) If discharges from a mechanical ventilation system may be hazardous, then you must maintain the drilling fluid-handling area at a negative pressure. You must protect the negative pressure area by using at least one of the following: a pressure-sensitive alarm, open-door alarms on each access to the area, automatic door-closing devices, air locks, or other devices approved by the District Supervisor;

(b) Gas detectors and alarms except in open areas where adequate ventilation is provided by natural means. You must test and recalibrate gas detectors quarterly. No more than 90 days may elapse between tests;

(c) Explosion-proof or pressurized electrical equipment to prevent the ignition of explosive gases. Where you use air for pressuring equipment, you must locate the air intake outside of and as far as practicable from hazardous areas; and

(d) Alarms that activate when the mechanical ventilation system fails.

#### **Other Drilling Requirements**

#### **§ 250.460 What are the requirements for conducting a well test?**

(a) If you intend to conduct a well test, you must include your projected plans for the test with your APD (form MMS-123) or in an Application for Permit to Modify (APM) (form MMS-124). Your plans must include at least the following information:

(1) Estimated flowing and shut-in tubing pressures;

(2) Estimated flow rates and cumulative volumes;

(3) Time duration of flow, buildup, and drawdown periods;

(4) Description and rating of surface and subsurface test equipment;

(5) Schematic drawing, showing the layout of test equipment;

(6) Description of safety equipment, including gas detectors and fire-fighting equipment;

(7) Proposed methods to handle or transport produced fluids; and

(8) Description of the test procedures.

(b) You must give the District Supervisor at least 24-hours notice before starting a well test.

#### **§ 250.461 What are the requirements for directional and inclination surveys?**

For this subpart, MMS classifies a well as vertical if the calculated average of inclination readings does not exceed 3 degrees from the vertical.

(a) *Survey requirements for a vertical well.* (1) You must conduct inclination surveys on each vertical well and record the results. Survey intervals may not exceed 1,000 feet during the normal course of drilling;

(2) You must also conduct a directional survey that provides both inclination and azimuth, and digitally record the results in electronic format:

(i) Within 500 feet of setting surface or intermediate casing;

(ii) Within 500 feet of setting any liner; and

(iii) When you reach total depth.

(b) *Survey requirements for directional well.* You must conduct directional surveys on each directional well and digitally record the results. Surveys must give both inclination and azimuth at intervals not to exceed 500 feet during the normal course of drilling. Intervals during angle-changing portions of the hole may not exceed 100 feet.

(c) *Measurement while drilling.* You may use measurement-while-drilling technology if it meets the requirements of this section.

(d) *Composite survey requirements.*

(1) Your composite directional survey must show the interval from the bottom of the conductor casing to total depth. In the absence of conductor casing, the survey must show the interval from the bottom of the drive or structural casing to total depth; and

(2) You must correct all surveys to Universal-Transverse-Mercator-Grid-north or Lambert-Grid-north after making the magnetic-to-true-north correction. Surveys must show the magnetic and grid corrections used and include a listing of the directionally computed inclinations and azimuths.

(e) If you drill within 500 feet of an adjacent lease, the Regional Supervisor may require you to furnish a copy of the well's directional survey to the affected leaseholder. This could occur when the adjoining leaseholder requests a copy of the survey for the protection of correlative rights.

#### **§ 250.462 What are the requirements for well-control drills?**

You must conduct a weekly well-control drill with each drilling crew. Your drill must familiarize the crew with its roles and functions so that all crew members can perform their duties promptly and efficiently.

(a) *Well-control drill plan.* You must prepare a well control drill plan for each well. Your plan must outline the assignments for each crew member and establish times to complete each portion of the drill. You must post a copy of the well control drill plan on the rig floor or bulletin board.

(b) *Timing of drills.* You must conduct each drill during a period of activity that minimizes the risk to drilling operations. The timing of your drills must cover a range of different operations, including drilling with a diverter, on-bottom drilling, and tripping.

(c) *Recordkeeping requirements.* For each drill, you must record the following in the driller's report:

(1) The time to be ready to close the diverter or BOP system; and

(2) The total time to complete the entire drill.

(d) *MMS ordered drill.* An MMS authorized representative may require you to conduct a well control drill during an MMS inspection. The MMS representative will consult with your onsite representative before requiring the drill.

#### **§ 250.463 Who establishes field drilling rules?**

(a) The District Supervisor may establish field drilling rules different from the requirements of this subpart when geological and engineering information shows that specific operating requirements are appropriate. You must comply with field drilling rules and nonconflicting requirements of this subpart. The District Supervisor may amend or cancel field drilling rules at any time.

(b) You may request the District Supervisor to establish, amend, or cancel field drilling rules.

#### **Applying for a Permit to Modify and Well Records**

#### **§ 250.465 When must I submit an Application for Permit to Modify (APM) or an End of Operations Report to MMS?**

(a) You must submit an APM (form MMS-124) or an End of Operations Report (form MMS-125) and other materials to the Regional Supervisor as shown in the following table. You must also submit a public information copy of each form.

When you	Then you must	And
(1) Intend to revise your drilling plan, change major drilling equipment, or plugback.	Submit form MMS-124 or request oral approval.	Receive written or oral approval from the District Supervisor before you begin the intended operation. If you get an approval, you must submit form MMS-124 no later than the end of the 3rd business day following the oral approval. In all cases, or you must meet the additional requirements in paragraph (b) of this section.
(2) Determine a well's final surface location, water depth, and the rotary kelly bushing elevation.	Immediately Submit a form MMS-124.	Submit a plat certified by a registered land surveyor that meets the requirements of § 250.412.
(3) Move a drilling unit from a wellbore before completing a well.	Submit forms Submit MMS-124 and MMS-125 within 30 days after the suspension of wellbore operations.	Submit appropriate copies of the well records.

(b) If you intend to perform any of the actions specified in paragraph (a)(1) of this section, you must meet the following additional requirements:

(1) Your form MMS-124 must contain a detailed statement of the proposed work that will materially change from the approved APD;

(2) Your form MMS-124 must include the present status of the well, depth of all casing strings set to date, well depth, present production zones and

productive capability, and all other information specified; and

(3) Within 30 days after completing this work, you must submit form MMS-124 with detailed information about the work to the District Supervisor, unless you have already provided sufficient information in a Well Activity Report, form MMS-133 (§ 250.468(b)).

#### **§ 250.466 What records must I keep?**

You must keep complete, legible, and accurate records for each well. You must keep drilling records onsite while

drilling activities continue. After completion of drilling activities, you must keep all drilling and other well records for the time periods shown in § 250.469. You may keep these records at a location of your choice. The records must contain complete information on all of the following:

(a) Well operations;

(b) Descriptions of formations penetrated;

(c) Content and character of oil, gas, water, and other mineral deposits in each formation;

(d) Kind, weight, size, grade, and setting depth of casing;

(e) All well logs and surveys run in the wellbore;

(f) Any significant malfunction or problem; and

(g) All other information required by the District Supervisor in the interests of resource evaluation, waste prevention, conservation of natural resources, and

the protection of correlative rights, safety, and environment.

#### **§ 250.467 How long must I keep records?**

You must keep records for the time periods shown in the following table.

You must keep records relating to	Until
(a) Drilling .....	Ninety days after you complete drilling operations.
(b) Casing and liner pressure tests, diverter tests, and BOP tests .....	Two years after the completion of drilling operations.
(c) Completion of a well or of any workover activity that materially alters the completion configuration or affects a hydrocarbon-bearing zone.	You permanently plug and abandon the well or until you forward the records with a lease assignment.

#### **§ 250.468 What well records am I required to submit?**

(a) You must submit copies of logs or charts of electrical, radioactive, sonic, and other well-logging operations; directional and vertical-well surveys; velocity profiles and surveys; and analysis of cores to MMS. Each Region will provide specific instructions for submitting well logs and surveys.

(b) For drilling operations in the GOM OCS Region, you must submit form MMS-133, Well Activity Report, to the District Supervisor on a weekly basis.

(c) For drilling operations in the Pacific or Alaska OCS Regions, you must submit form MMS-133, Well Activity Report, to the District Supervisor on a daily basis.

#### **§ 250.469 What other well records could I be required to submit?**

The Regional or District Supervisor may require you to submit copies of any or all of the following well records.

(a) Well records as specified in § 250.466;

(b) Paleontological interpretations or reports identifying microscopic fossils by depth and/or washed samples of drill cuttings that you normally maintain for paleontological determinations. The Regional Supervisor may issue a Notice

to Lessees that prescribes the manner, timeframe, and format for submitting this information;

(c) Service company reports on cementing, perforating, acidizing, testing, or other similar services; or

(d) Other reports and records of operations.

#### **Hydrogren Sulfide**

\* \* \* \* \*

9. In the newly redesignated § 250.490, paragraphs (g)(4)(iv), (j)(13)(ii), and (p)(2) are revised to read as follows:

#### **§ 250.490 Hydrogen sulfide.**

\* \* \* \* \*

(g) \* \* \*

(4) \* \* \*

(iv) Restrictions and corrective measures concerning beards, spectacles, and contact lenses in conformance with ANSI Z88.2, American National Standard for Respiratory Protection (incorporated by reference as specified in § 250.198);

\* \* \* \* \*

(j) \* \* \*

(13) \* \* \*

(ii) Design, select, use, and maintain respirators in conformance with ANSI

Z88.2 (incorporated by reference as specified in § 250.198).

\* \* \* \* \*

(p) \* \* \*

(2) Use BOP system components, wellhead, pressure-control equipment, and related equipment exposed to H<sub>2</sub>S-bearing fluids in conformance with NACE Standard MR0175-99 (incorporated by reference as specified in § 250.198).

\* \* \* \* \*

#### **§ 250.504 [Amended]**

10. In § 250.504, in the first and last sentences, the citation “§ 250.417” is revised to read “§ 250.490”.

#### **§ 250.513 [Amended]**

11. In § 250.513, the following changes are made:

A. In paragraph (a), the citation “§ 250.414” is revised to read “§ 250.410 through § 250.418”.

B. In paragraph (b)(4), the citation “§ 250.417” is revised to read “§ 250.490”.

12. In § 250.515, paragraph (b) is revised to read as follows:

#### **§ 250.515 Blowout prevention equipment.**

\* \* \* \* \*

(b) The minimum BOP system for well-completion operations must meet the appropriate standards from the following table:

When	The minimum BOP stack must include
(1) The expected pressure is less than 5,000 psi.	Three BOPs consisting of an annular, one set of pipe rams, and one set of blind or blind-shear rams.
(2) The expected pressure is 5,000 psi or greater or you use multiple tubing strings.	Four BOPs consisting of an annular, two sets of pipe rams, and one set of blind or blind-shear rams.
(3) You handle multiple tubing strings simultaneously.	Four BOPs consisting of an annular, one set of pipe rams, one set of dual pipe rams, and one set of blind or blind-shear rams.
(4) You use a tapered drill string .....	At least one set of pipe rams that are capable of sealing around each size of drill string. If the expected pressure is greater than 5,000 psi, then you must have at least two sets of pipe rams that are capable of sealing around the larger size drill string. You may substitute one set of variable bore rams for two sets of pipe rams.
(5) It is after February 21, 2006 .....	At least one set of blind-shear rams. The blind-shear rams must be capable of shearing the drill pipe or tubing in the hole.

\* \* \* \* \*

**§ 250.604 [Amended]**

13. In § 250.604, in the first and last sentences, the citation “§ 250.417” is revised to read “§ 250.490”.

**§ 250.613 [Amended]**

14. In § 250.613(b)(3), the citation “§ 250.417” is revised to read “§ 250.490”.

15. In § 250.615, paragraph (b) is revised to read as follows:

**§ 250.615 Blowout prevention equipment.**

\* \* \* \* \*

(b) The minimum BOP system for well-workover operations with the tree removed must meet the appropriate standards from the following table:

When	The minimum BOP stack must include
(1) The expected pressure is less than 5,000 psi.	Three BOPs consisting of an annular, one set of pipe rams, and one set of blind or blind-shear rams.
(2) The expected pressure is 5,000 psi or greater or you use multiple tubing strings.	Four BOPs consisting of an annular, two sets of pipe rams, and one set of blind or blind-shear rams.
(3) You handle multiple tubing strings simultaneously.	Four BOPs consisting of an annular, one set of pipe rams, one set of dual pipe rams, and one set of blind or blind-shear rams.
(4) You use a tapered drill string .....	At least one set of pipe rams that are capable of sealing around each size of drill string. If the expected pressure is greater than 5,000 psi, then you must have at least two sets of pipe rams that are capable of sealing around the larger size drill string. You may substitute one set of variable bore rams for two sets of pipe rams.
(5) It is after February 21, 2006 .....	At least one set of blind-shear rams. The blind-shear rams must be capable of shearing the drill pipe or tubing in the hole.

**§ 250.807 [Amended]**

16. In § 250.807, the citation “§ 250.417” is revised to read “§ 250.490”.

**§ 250.1105 [Amended]**

17a. In § 250.1105(f)(1)(i), the citation “§ 250.417(f)” is revised to read “§ 250.490(f)”.

**§ 250.1604 [Amended]**

17b. In § 250.1604 in paragraph (b), in the first and third sentences, the citation “§ 250.417” is revised to read “§ 250.490”.

**§ 250.1612 [Amended]**

18. In § 250.1612, the citation “§ 250.408” is revised to read “§ 250.462”.

**§ 250.1614 [Amended]**

19. In § 250.1614, in paragraph (b), the citation “§ 250.410(b), (c), (d), and (e)” is revised to read “§ 250.455 through § 250.459”; and the citation “§ 250.410(b)(8)” is revised to read “§ 250.456(g)”.

[FR Doc. 03-3425 Filed 2-19-03; 8:45 am]

BILLING CODE 4310-MR-P





# Federal Register

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**Thursday,  
February 20, 2003**

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## **Part IV**

# **Securities and Exchange Commission**

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**17 CFR Part 270**

**Custody of Investment Company Assets  
With a Securities Depository; Final Rule**

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 270

[Release No. IC-25934; File No. S7-22-01]

RIN 3235-AG71

### Custody of Investment Company Assets With a Securities Depository

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Final rule.

**SUMMARY:** The Commission is adopting amendments to the rule under the Investment Company Act of 1940 that governs investment companies' use of securities depositories. The amendments expand the types of investment companies that may maintain assets with a depository, and update the conditions they must follow to use a depository. The amendments respond to developments in securities depository practices and commercial law since the rule was adopted.

**EFFECTIVE DATES:** The amendments are effective on March 28, 2003. The incorporation by reference of certain definitions listed in the rule is approved by the Director of the Federal Register as of March 28, 2003.

**FOR FURTHER INFORMATION CONTACT:** Hugh P. Lutz, Attorney, or C. Hunter Jones, Assistant Director, Office of Regulatory Policy, at (202) 942-0690, in the Division of Investment Management, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549-0506.

**SUPPLEMENTARY INFORMATION:** The Commission today is adopting amendments to rule 17f-4 [17 CFR 270.17f-4] under the Investment Company Act of 1940 [15 U.S.C. 80a] (the "Investment Company Act" or the "Act").<sup>1</sup>

#### Table of Contents

#### Executive Summary

#### I. Background

#### II. Discussion

- A. U.S. Depositories
- B. Reliance on Rule by Non-Management Companies; Approval of Custody Arrangements
- C. Compliance Requirements for the Custodian or Securities Depository
- D. Treatment of U.S. and Foreign Depositories

#### III. Cost-Benefit Analysis

#### IV. Effects on Efficiency, Competition, and Capital Formation

#### V. Summary of Final Regulatory Flexibility Analysis

VI. Paperwork Reduction Act  
VII. Statutory Authority  
Text of Rule

### Executive Summary

The Commission today is adopting amendments to rule 17f-4 under the Investment Company Act, the rule that permits a registered management investment company ("fund") to deposit the securities it owns in a system for the central handling of securities ("securities depository"). The custody practices and commercial law that relate to custody arrangements have changed substantially since we adopted the rule in 1978, and the amendments update and simplify rule 17f-4 to reflect these business and legal developments. The amendments permit additional types of investment companies to rely on the rule, and allow depositories to perform additional functions under the rule. The amendments also eliminate a number of specific custodial compliance requirements of rule 17f-4, and require instead that a fund's custodian, when using a depository, exercise due care in accordance with reasonable commercial standards.

### I. Background

Section 17(f) of the Investment Company Act governs the custody of a fund's assets, including its portfolio securities.<sup>2</sup> This section requires a fund to maintain its securities and other investments with certain types of custodians under conditions designed to assure the safety of the fund's assets. It permits a fund to maintain its securities in a system for the central handling of securities (commonly referred to as a "securities depository"), subject to rules adopted by the Commission.<sup>3</sup>

The Commission adopted rule 17f-4 in 1978 to establish conditions for the use of securities depositories by funds.<sup>4</sup> The conditions were designed to limit

potential risks to funds using securities depositories, and were drafted to be compatible with the 1978 revisions to Article 8 of the Uniform Commercial Code ("UCC"), which covers the ownership and transfer of investment securities under state law.<sup>5</sup> Since 1978, securities custody practices have changed substantially, as more investors (including funds) have come to hold their securities with depositories such as the Depository Trust Company, either directly or through an intermediary. In 1994, Article 8 was substantially revised to clarify the legal rights of funds and other investors that use securities depositories.<sup>6</sup> In addition, experience with depositories during this period has shown that the use of depositories raises substantially fewer risks than had been apparent in 1978.

In November 2001, we proposed amendments to rule 17f-4 to reflect these significant developments.<sup>7</sup> We received six comment letters on the proposal.<sup>8</sup> Commenters generally favored the amendments, but also recommended several changes that they believed would improve the interaction

<sup>5</sup> See UCC, 1978 Official Text with Comments, Article 8, Investment Securities (West 1978) ("Prior Article 8"); Use of Depository Systems by Registered Management Companies, Investment Company Act Release No. 10053 (Dec. 8, 1977) [42 FR 63722 (Dec. 19, 1977)] ("1977 Reproposing Release") at nn.4-7, 9, 12 and accompanying text (citing provisions of Prior Article 8); 1978 Adopting Release, *supra* note 4, at nn.4 and 6.

<sup>6</sup> Prior Article 8 assumed that issuers would record investors' interests on their own books. Today, investors typically maintain a security through an account with a broker-dealer, bank or other financial institution ("securities intermediary"), which in turn will maintain an account for its customers with a securities depository. The depository generally does not record each investor's interest, but records the interest of the intermediary on behalf of all of its customers. Thus, the individual investor's interest (or "security entitlement") appears only on the books of the intermediary with which the investor maintains an account. Revised Article 8 refers to this type of securities ownership arrangement as an "indirect holding" arrangement, as distinguished from a "direct holding" arrangement in which the investor's ownership interest appears on the issuer's books. See Uniform Commercial Code, Revised Article 8—Investment Securities (With Conforming and Miscellaneous Amendments to Articles 1, 4, 5, 9, and 10) (1994 Official Text with Comments) ("Revised Article 8"). Revised Article 8 has been adopted by all 50 states, the District of Columbia, and Puerto Rico.

<sup>7</sup> See Custody of Investment Company Assets With a Securities Depository, Investment Company Act Release No. 25266 (Nov. 15, 2001) [66 FR 58412 (Nov. 15, 2001)] ("Proposing Release"), at nn.4-19 and accompanying text, for a more detailed discussion of Prior Article 8 and Revised Article 8.

<sup>8</sup> We received the six comment letters from three commenters. Each of the commenters wrote an initial letter, and an additional letter discussing points raised by the other commenters. The comment letters are available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, NW, Washington, DC (File No. S7-22-01).

<sup>1</sup> Unless otherwise noted, all references to "rule 17f-4" or any paragraph of the rule will be to 17 CFR 270.17f-4, as amended.

<sup>2</sup> 15 U.S.C. 80a-17(f).

<sup>3</sup> In 1999, the Gramm-Leach-Bliley Act, Pub. L. 106-102, 113 Stat. 1338 (1999), added section 17(f)(6) to the Investment Company Act. Section 17(f)(6) authorizes the Commission to prescribe conditions under which a bank-sponsored fund may maintain fund assets with an affiliated bank. This section is intended to allow the Commission to address self-custody issues such as conflicts of interest and misappropriation of fund assets that could arise when a fund holds its assets with an affiliated bank custodian. The amendments to rule 17f-4 affect the ability of all funds and their custodians to use certain depositories. The amendments do not address specific issues that arise when a fund maintains assets with an affiliated bank custodian, and we are not relying on the authority contained in section 17(f)(6) in adopting these amendments.

<sup>4</sup> See Deposits of Securities in Securities Depositories, Investment Company Act Release No. 10453 (Oct. 26, 1978) [43 FR 50869 (Nov. 1, 1978)] ("1978 Adopting Release").

of the rule with Revised Article 8. In addition, commenters disagreed on whether our rules governing a fund's use of foreign custodians and depositories should apply when a fund holds securities with a U.S. depository that itself holds the securities with a foreign custodian or depository.<sup>9</sup> We are adopting new rule 17f-4 with modifications that respond to many of the issues raised by the commenters.

## II. Discussion

Rule 17f-4 permits funds to place and maintain "financial assets" corresponding to the fund's "securities entitlements"<sup>10</sup> with a securities depository subject to certain conditions, discussed below.<sup>11</sup> As suggested by a commenter, we have drafted the rule to employ terms used by Revised Article 8 to assure the rule will interact well with that Article, which, as we noted above, is the primary law governing securities ownership under state law.<sup>12</sup>

### A. U.S. Depositories

Rule 17f-4 permits funds to keep and maintain securities and other assets in a "securities depository" subject to regulation in the United States.<sup>13</sup> Under the rule, a "securities depository" is a "clearing corporation" that is registered with the Commission as a clearing

agency,<sup>14</sup> or a federal reserve bank or other person authorized to operate the federal book-entry system for U.S. Treasury securities. At the suggestion of a commenter, we simplified the definition to describe what a depository is rather than what it does. The rule no longer restricts the functions that a depository may perform. As a result, a fund may use a depository that holds securities that are acquired or disposed of by bookkeeping entry as well as those that are conveyed by physical delivery.

### B. Reliance on Rule by Non-Management Companies; Approval of Custody Arrangements

The amendments expand rule 17f-4 to permit any registered investment company, including a unit investment trust ("UIT") or a face-amount certificate company, to use a securities depository.<sup>15</sup> The amendments also eliminate from the rule the requirement that fund directors approve arrangements with depositories, which

today largely are routine matters. Commenters supported these changes.<sup>16</sup>

### C. Compliance Requirements for the Custodian or Securities Depository

The amendments also eliminate, as proposed, the specific safeguarding requirements that have been in rule 17f-4, and substitute two more general obligations.<sup>17</sup> First, a fund's custodian must be obligated, at a minimum, to exercise due care in accordance with reasonable commercial standards in discharging its duty as a "securities intermediary" to obtain and thereafter maintain financial assets.<sup>18</sup> If the fund deals directly with a depository, the depository's contract or rules for participants must provide that the depository will meet similar obligations.<sup>19</sup> This condition thus incorporates the minimum standard of care that Revised Article 8 sets forth for circumstances where the parties have not agreed to a standard.<sup>20</sup>

Second, the custodian must provide, promptly upon request by the fund, such reports as are available about the internal accounting controls and

<sup>14</sup> A clearing agency is "any person who acts as an intermediary in making payments or deliveries or both in connection with transactions in securities or who provides facilities for comparison of data respecting the terms of settlement of securities transactions, to reduce the number of settlements of securities transactions, or for the allocation of securities settlement responsibilities. Such term also means any person, such as a securities depository, who (i) acts as a custodian of securities in connection with a system for the central handling of securities whereby all securities of a particular class or series of any issuer deposited within the system are treated as fungible and may be transferred, loaned or pledged by bookkeeping entry without physical delivery of securities certificates, or (ii) otherwise permits or facilitates the settlement of securities transactions or the hypothecation or lending of securities without physical delivery of securities certificates." 15 U.S.C. 78c(23)(A).

<sup>15</sup> Rule 17f-4(c)(3). In addition to expanding the types of funds that could rely on rule 17f-4, the Proposing Release would have expanded the types of organizations that could operate as depositories under the rule. The Proposing Release would have allowed a registered transfer agent to operate as a securities depository for purposes of holding shares of other funds. See Proposing Release, *supra* note 7, at nn.29-31 and accompanying text. All of the commenters raised issues concerning this proposed change. Two argued that a fund's use of another fund's transfer agent involves self-custody issues that could be addressed in conjunction with rule 17f-2 [17 CFR 270.17f-2], the rule governing fund self-custody arrangements. In light of the issues raised by commenters, we have decided not to adopt the amendment related to mutual fund transfer agents, but instead intend to consider these issues in connection with any future revisions to rule 17f-2. Until then, funds should continue to rely on the staff no-action letters that address arrangements in which funds invest in shares of other funds. See, e.g., United States Trust Co. of New York, SEC Staff No-Action Letter (Apr. 16, 1992) (staff stated it would not recommend enforcement action if trustee maintained UIT's investments in open-end funds with transfer agents of portfolio funds under conditions based on rule 17f-4).

<sup>16</sup> At the suggestion of one commenter, we have eliminated the requirement we included in the proposed amendments that a fund officer approve a depository arrangement. The requirement is unnecessary because a fund officer (or a person with similar authority) would have to execute agreements necessary to permit the fund to use the depository. See section 17(f)(2) of the Investment Company Act [15 U.S.C. 80a-17(f)(2)] (requiring that a fund consent to its custodian's deposit of securities with a depository).

<sup>17</sup> These specific requirements were the earmarking, segregation, confirmation, and successor custodian requirements. For a detailed discussion of these requirements, see Proposing Release, *supra* note 7, at nn.39-46.

<sup>18</sup> Rule 17f-4(a)(1). We proposed to require a custodian using a depository to "take all actions reasonably necessary or appropriate under applicable commercial or regulatory law" to safeguard fund assets. See Proposing Release, *supra* note 7, at nn.48-51 and accompanying text. Two commenters suggested that a better approach to accomplish the intent of that provision would be to require the custodian, as a securities intermediary, to take reasonable steps to preserve rights of the fund as an entitlement holder in financial assets held by the depository. One of these commenters urged us to incorporate into the rule the standard of care provided for by section 504(c) of Article 8 when the parties have not agreed to a standard. Section 504(c) provides that a securities intermediary satisfies the duty relating to maintaining a financial asset in those circumstances if it "exercises due care in accordance with reasonable commercial standards to obtain and maintain the financial asset." This standard is reflected in the rule.

<sup>19</sup> Rule 17f-4(b)(1)(i).

<sup>20</sup> One commenter questioned our authority to establish compliance requirements for custodians. Section 17(f)(2) of the Investment Company Act authorizes the Commission to adopt rules that establish conditions under which a "registered management company or any \* \* \* custodian" may deposit securities with a securities depository.

<sup>9</sup> See *infra* Section II.D.

<sup>10</sup> The amended rule incorporates the definition of "security entitlement" contained in Revised Article 8. See rule 17f-4(c)(1). A security entitlement means "the rights and property interest of an entitlement holder with respect to a financial asset" in an indirect holding arrangement. See Revised Article 8, *supra* note 6, section 8-102(a)(17). A security entitlement gives the investor a limited pro rata property interest in comparable entitlements (or other interests in securities) maintained by the investor's intermediary with a depository or other intermediary. See *id.*, section 8-503(b) and cmt. 1, and section 8-504 and cmt. 1 (all customers of the securities intermediary share a pro rata property interest in all interests in the same financial asset held by the intermediary).

<sup>11</sup> In addition, the amendments permit a custodian to use an intermediary custodian. See rule 17f-4(a).

<sup>12</sup> The proposed amendments would have defined a securities depository as a "system for the central handling of assets in which those assets are treated as fungible and are transferred, pledged, or otherwise acquired or disposed of by bookkeeping entry without physical delivery, or by physical delivery within or through the system." See Proposing Release, *supra* note 7 at n.22 and accompanying text. One commenter stated that we could accomplish the same objectives by simply amending the rule to define securities depository by reference to a "clearing corporation" under Article 8 and a "clearing agency" under the Securities Exchange Act of 1934. We agree that this change simplifies the rule text and embodies relevant terms defined elsewhere in the federal securities laws, and the amended rule therefore reflects this revision.

<sup>13</sup> The use of foreign depositories by funds is governed by rule 17f-7 [17 CFR 270.17f-7].

financial strength of the custodian.<sup>21</sup> If the fund deals directly with a depository, the depository's contract or written rules for its participants must provide that the depository will provide similar financial reports.<sup>22</sup>

#### *D. Treatment of U.S. and Foreign Depositories*

The Depository Trust Company ("DTC"), the predominant U.S. securities depository, has established linkages with several foreign custodians and depositories through which it holds assets with those foreign institutions. In the Proposing Release, we requested comment on whether a fund, when it holds securities with a U.S. depository that are ultimately custodied with a foreign custodian or depository, should be subject to rules 17f-5 or 17f-7,<sup>23</sup> which establish conditions for the custody of fund assets with foreign custodians and depositories.<sup>24</sup>

Three commenters responded to our request. One commenter, an association of global custodian banks, argued that the failure of the Commission to extend the requirements of rules 17f-5 and 17f-7 would permit funds to circumvent these rules and would deny fund investors the protections of the rules. The Investment Company Institute and DTC opposed the application of the foreign custody rules. They pointed out that U.S. depositories are regulated by the Commission as registered clearing agencies, and that any linkages between them and foreign custodians and depositories are subject to our approval and monitoring. They argued that further regulation would increase the burden on these domestic depositories without enhancing the protection of fund assets.

We have decided not to revise the rule to require the application of our foreign custody rules when a fund holds securities through a U.S. depository that has a linkage to a foreign custodian or depository. As we explained in the Proposing Release, U.S. depositories register with us as clearing agencies under the Securities Exchange Act of

1934,<sup>25</sup> and are subject to rigorous standards for their operations.<sup>26</sup> We approve each proposed linkage to a foreign custodian or depository only when the custodian or depository will provide a level of protection equivalent to that which a U.S. clearing agency must provide.<sup>27</sup> This is a standard considerably higher than we require fund boards to apply in selecting a foreign custodian.<sup>28</sup> We agree with the commenters who argued that the application of the foreign custody rules would impose regulatory burdens without appreciably enhancing the protection of fund assets.<sup>29</sup>

### **III. Cost-Benefit Analysis**

The Commission is sensitive to the costs and benefits that result from its rules. As discussed above, the amendments to rule 17f-4 respond to developments in securities custody practices and commercial law that have occurred since the rule was adopted. The amendments expand the types of funds that may rely on the rule, update the rule's compliance requirements, and reduce burdens on fund directors. In the Proposing Release, we requested comment and specific data regarding the costs and benefits of the proposed amendments. We received one comment on the costs and benefits of the amendments. The comment is discussed below.

<sup>25</sup> See section 17A of the Securities Exchange Act [15 U.S.C. 78q-1].

<sup>26</sup> See Proposing Release, *supra* note , at n.73 and accompanying text.

<sup>27</sup> See, e.g., Self-Regulatory Organizations; The Depository Trust Company, Securities Exchange Act Release No. 39657 (Feb. 12, 1998) [63 FR 8725 (Feb. 20, 1998)] (notice of proposed link between DTC and Canadian securities depository); Self-Regulatory Organizations; The Depository Trust Company, Securities Exchange Act Release No. 40523 (Oct. 6, 1998) [63 FR 54739 (Oct. 13, 1998)] (order approving proposed link).

<sup>28</sup> Rule 17f-5 generally requires that a fund's board of directors or its delegate determine that (i) a fund's financial assets will be subject to reasonable care, based on the standards applicable in the relevant market, and (ii) the arrangement with the foreign custodian is governed by a written contract that meets specified standards.

<sup>29</sup> Similarly, we have not revised rule 17f-4 to except a fund from the foreign custody rules if the fund maintains financial assets with a foreign custodian or depository with which a U.S. depository has established a link that we have approved. One commenter suggested in an earlier letter that the costs of complying with the foreign custody rules are relatively fixed, and that the addition or subtraction of institutions therefore would not have a significant effect on those costs. See Letter from Daniel L. Goelzer, Baker & McKenzie, to C. Hunter Jones, SEC, at p.4 (Oct. 17, 2001). Moreover, the analysis required by rule 17f-7 can provide custodians and funds with current information regarding a foreign depository's expertise and market reputation, the quality of its services, and its financial strength. This information can play an important role in any future custody decisions made by funds and their advisers.

#### *A. Benefits*

The Commission staff estimates that approximately 5,155 entities (including 5,000 registered investment companies, 130 custodians, and 25 possible securities depositories) would benefit from the amendments.<sup>30</sup>

*Removes specific custodial compliance requirements.* The amendments to rule 17f-4 remove three custodial compliance requirements<sup>31</sup> that have accounted for a significant amount of custodians' time and resources. The Commission staff estimates that custodians currently spend approximately 66,300 hours<sup>32</sup> and \$3,694,600<sup>33</sup> annually to comply with these three requirements. In place of these costly requirements, the amendments provide that a fund's custodian, when using a depository, must at a minimum exercise due care in accordance with reasonable commercial standards and that custodians (or securities depositories) provide reports on internal accounting controls to funds. The new compliance requirements are much less prescriptive than those previously contained in rule 17f-4, which will allow custodians some flexibility in determining the most efficient method of safeguarding financial assets. The reduction in the compliance burdens in rule 17f-4 may ultimately benefit fund investors through reduced costs.

*Reduces burdens on fund directors.* The amendments to rule 17f-4 eliminate the requirement that fund directors approve all custody arrangements and changes to those arrangements. The amendments will benefit fund directors and fund shareholders by eliminating the need for fund directors to approve arrangements that have become increasingly routine. The elimination of this requirement will free directors to

<sup>30</sup> These estimates are based on statistics compiled by Commission staff from January 1, 2002 through December 31, 2002.

<sup>31</sup> The three custodial compliance requirements are the segregation, earmarking, and confirmation requirements.

<sup>32</sup> The staff estimates that, in order to comply with the rule, each custodian spends about 10 hours segregating, 250 hours earmarking, and 250 hours on daily confirmations to funds. (510 hours × 130 custodians = 66,300 total hours by all custodians).

<sup>33</sup> The following is an estimated breakdown of the annual cost for custodians to comply with the three compliance requirements:

Segregation—10 total hours: 5 hours of support staff and 5 hours by professional staff.

Earmarking—250 hours: 125 hours of support staff and 125 hours of professional staff.

Daily Confirmations—250 hours: 250 hours of support staff.

Total: 380 hours of support staff (\$31 per hour) and 130 hours of professional staff (\$128 per hour). (380 × \$31) + (130 × \$128) = \$28,420 + 130 custodians = \$3,694,600.

<sup>21</sup> Rule 17f-4(a)(2). As proposed, rule 17f-4 also would have required custodians to provide available reports on the internal accounting controls of any securities depository (or its operator) and any intermediate custodian. In response to comments questioning funds' need for these financial reports, we are not adopting the proposed provision. Because Revised Article 8 generally limits a fund's recourse to its own custodian, reports on intermediaries with which it does not directly deal are likely to be less important to the fund.

<sup>22</sup> Rule 17f-4(b)(1)(ii).

<sup>23</sup> 17 CFR 270.17f-5, 270.17f-7.

<sup>24</sup> See Proposing Release, *supra* note 7, at nn.67-76 and accompanying text.

spend more time on other, more significant matters.

*Updates the rule to reflect current custody practices and commercial law.* The amendments to rule 17f-4 will benefit funds, advisers, and custodians by updating the rule to conform to current custody practices and commercial law. As discussed above, rule 17f-4 was adopted in 1978 and was designed to operate in the context of commercial law applicable at that time. Custody practices and commercial law have changed significantly since 1978, and the amendments reflect these developments.

The Commission staff has issued numerous no-action letters in an attempt to keep the rule current with custody practice and commercial law.<sup>34</sup> The amendments will make the rule more transparent by eliminating the need for funds to rely on the staff's no-action letters, and will resolve current and future ambiguities that have arisen and are sure to arise between the application of Revised Article 8 and rule 17f-4.

*Expands functions of securities depositories.* The amendments expand the functions that a securities depository may perform on behalf of a fund.<sup>35</sup> These amendments therefore may facilitate the use of centralized custody arrangements for investments. Costs would be reduced in the clearing and settlement process, because it is easier to clear and settle transactions with an entity that can hold almost all the assets of the fund, rather than with several entities that hold separate portions of fund assets. Reducing the costs and fees associated with securities depositories and custodians will benefit investors.

#### B. Costs

The Proposing Release identified one provision in the rule that would impose costs—the requirement that custody contracts be modified to reflect the rule's new, general compliance requirements.<sup>36</sup> One commenter objected to the contract amendment language, and instead recommended that the rule allow the affected parties to determine the specific means of compliance. In response to this comment, we have modified the relevant regulatory language to state that the custodian must be “at a minimum obligated” to exercise due care in accordance with reasonable commercial

standards in discharging its duty to obtain and thereafter maintain financial assets.<sup>37</sup> This change provides custodians and funds with some flexibility in determining the specific means of compliance with the rule. The requirements of the rule could be met, for instance, by simply having the custodian send a letter to the fund, citing as consideration the continued ability of the custodian to provide custodial services for the fund. The costs associated with this method of compliance would be minimal.<sup>38</sup>

Rule 17f-4 requires that custodians (or securities depositories) provide reports on internal accounting controls to funds. The costs associated with providing copies of existing reports to funds should be minimal. The amendments do not require the preparation of new reports.

#### IV. Effects on Efficiency, Competition, and Capital Formation

Section 2(c) of the Investment Company Act requires the Commission, when it engages in rulemaking and is required to determine whether an action is consistent with the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.<sup>39</sup> The Commission has considered these factors.

As noted above, we received three letters on whether a fund, when it holds securities that are ultimately custodied with a foreign custodian or depository, should be subject to rules 17f-5 or 17f-7. We have decided not to apply the foreign custody rules in these circumstances in part because U.S. depositories are regulated by the Commission as registered clearing agencies, and it would be inefficient to subject these depositories to the additional requirement in rules 17f-5 and 17f-7.<sup>40</sup>

The rule amendments should promote efficiency by eliminating the restrictions on the functions that a depository may perform. The amendments permit a fund to use a depository that holds securities that are acquired or disposed of by bookkeeping entry as well as those that are conveyed by physical delivery. The amendments therefore should facilitate the use of centralized custody arrangement for investors. This change may promote efficiency because it is

easier and less costly to clear and settle transactions with a single entity that can hold almost all of the assets of a fund, rather than with several entities. In addition, the rule amendments will promote efficiency by eliminating the requirement that fund directors approve custody arrangements, which will allow directors to focus on other, more important matters, and by eliminating four custodial compliance requirements that are no longer necessary for the protection of fund assets.

The rule amendments will not have a significant impact on competition and capital formation. The amendments may marginally promote competition by permitting all registered investment companies, including UITs and face-amount certificate companies, to rely on the rule. As noted above, previously only registered management investment companies could use a securities depository under the rule.

#### V. Summary of Final Regulatory Flexibility Analysis

We have prepared a Final Regulatory Flexibility Analysis (“FRFA”) in accordance with 5 U.S.C. 604, related to the amendments to rule 17f-4 under the Investment Company Act of 1940 that we are adopting today. A summary of the Initial Regulatory Flexibility Analysis (“IRFA”), which was prepared in accordance with 5 U.S.C. 603, was published in the Proposing Release.<sup>41</sup> Copies of the FRFA and the IRFA may be obtained by contacting Hugh P. Lutz, Attorney, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549-0506

##### A. Need for Rule Amendments

The FRFA summarizes the background of the amendments. The FRFA also discusses the reasons for the new rule and amendments and the objectives of, and legal basis for, these rulemaking initiatives. Those items are discussed above in this Release.<sup>42</sup> The FRFA discusses the effect of the amendments on small entities.

##### B. Significant Issues Raised by Public Comment

The Commission received no comments on the IRFA.

##### C. Small Entities Subject to the Rule Amendments

The FRFA addresses the effect that amendments to rule 17f-4 will have on small entities. For purposes of the

<sup>37</sup> Rule 17f-4(a)(1).

<sup>38</sup> Approximately 49 funds deal directly with securities depositories. In these cases, compliance with rule 17f-4 can occur simply by having the depository modify its written rules for its participants, if necessary.

<sup>39</sup> 15 U.S.C. 80a-2(c).

<sup>40</sup> See *supra* Section II.D.

<sup>41</sup> See Proposing Release, *supra* note, at Section VI.

<sup>42</sup> See *supra* Section II.

<sup>34</sup> See Proposing Release, *supra* note, at nn.30-34 and accompanying text.

<sup>35</sup> See *supra* Section II.A.

<sup>36</sup> See Proposing Release, *supra* note, at nn.85-89 and accompanying text.

Regulatory Flexibility Act,<sup>43</sup> a fund is a small entity if the fund, together with other funds in the same group of related funds, has net assets of \$50 million or less as of the end of its most recent fiscal year.<sup>44</sup> Approximately 4,850 registered investment companies, including approximately 233 registered investment companies that are small entities, will be affected by amended rule 17f-4.<sup>45</sup> Approximately 130 custodians, most of which are banks or registered broker-dealers, will be affected by rule 17f-4. Few if any of these custodians are small entities.<sup>46</sup> Approximately 25 entities that could serve as securities depositories will be affected by the rule;<sup>47</sup> few if any of these entities are small entities. The rule imposes conditions for the use of securities depositories by all funds regardless of the size of the fund, its custodian, or the securities depository. The risks attendant to funds' use of securities depositories do not vary based on the size of the entities involved.

#### *D. Projected Reporting, Recordkeeping, and Other Compliance Requirements*

The amendments will significantly ease rule 17f-4's reporting, recordkeeping, and other compliance requirements. The amendments eliminate a number of specific requirements<sup>48</sup> and substitute two general compliance requirements for custodians and depositories.<sup>49</sup> First, the custodian must, at a minimum, exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain financial assets.<sup>50</sup> If the fund deals directly with a depository, the fund's contract with the securities depository (or the depository's own written rules for its participants) must provide that the depository will meet similar obligations.<sup>51</sup> Second, the custodian must provide, promptly upon request by

the fund, such reports as are available about the internal accounting controls and financial strength of the custodian.<sup>52</sup> If the fund deals directly with a depository, the depository's contract or written rules for its participants must provide that the depository will provide similar financial reports.<sup>53</sup>

#### *E. Duplicative, Overlapping or Conflicting Federal Rules*

The Commission believes that there are no federal rules that duplicate, overlap, or conflict with the rule amendments.

#### *F. Agency Action to Minimize Effect on Small Entities*

In connection with the amendments, the Commission considered the following alternatives: (i) Establishing different compliance or reporting standards that take into account the resources available to small entities; (ii) clarifying, consolidating or simplifying the compliance requirements for small entities; (iii) using performance rather than design standards; and (iv) exempting small entities from coverage of all or part of the rule.

We do not believe that special compliance, timetable, or reporting requirements or an exemption from coverage of the rule for small entities would be consistent with investor protection. Similarly, any further clarification, consolidation, or simplification of the reporting requirements for small entities could compromise the safeguards embodied in the new rule and amendments. The rule amendments use performance, rather than design standards, in the sense that the amendments require that custodians exercise due care in accordance with reasonable commercial standards in discharging their duty as a securities intermediary to obtain and thereafter maintain financial assets.

#### **VI. Paperwork Reduction Act**

As explained in the Proposing Release, certain provisions of the amendments to rule 17f-4 contain "collection of information" requirements within the meaning of the Paperwork Reduction Act [44 U.S.C. 3501-3520] ("PRA"). We published notice soliciting comments on the collection of information requirements in the Proposing Release and submitted these requirements to the Office of Management and Budget ("OMB") for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The title for

the collection of information is "Custody of Investment Company Assets with a Securities Depository." An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. The OMB control number for rule 17f-4 is 3235-0225.

As discussed above, today we are adopting amendments to rule 17f-4 that are substantially similar to the amendments that we proposed in November 2001. The amendments permit additional types of investment companies to rely on the rule, and allow depositories to perform additional functions under the rule. The amendments also eliminate a number of specific custodial compliance requirements of rule 17f-4, and substitute two more general compliance requirements. None of the commenters addressed the PRA burden associated with these amendments.

#### **VII. Statutory Authority**

The Commission is amending rule 17f-4 pursuant to the authority set forth in sections 6(c), 17(f), 26, 28, 30, 31, and 38(a) of the Investment Company Act of 1940 [15 U.S.C. 80a-6(c), 80a-17(f), 80a-26, 80a-28, 80a-29, 80a-30, and 80a-37(a)].

#### **Text of Rule**

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is revised to read as follows:

#### **List of Subjects in 17 CFR Part 270**

Incorporation by reference, Investment companies, Reporting and recordkeeping requirements, Securities.

#### **PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940**

1. The authority citation for Part 270 continues to read, in part, as follows:

**Authority:** 15 U.S.C. 80a-1 *et seq.*, 80a-34(d), 80a-37, and 80a-39, unless otherwise noted;

\* \* \* \* \*

2. Section 270.17f-4 is revised to read as follows:

#### **§ 270.17f-4 Custody of investment company assets with a securities depository.**

(a) *Custody arrangement with a securities depository.* A fund's custodian may place and maintain financial assets, corresponding to the fund's security entitlements, with a securities depository or intermediary custodian, if the custodian:

<sup>43</sup> 5 U.S.C. 601-612.

<sup>44</sup> 17 CFR 270.0-10.

<sup>45</sup> There are approximately 5,000 registered investment companies, including 240 small entities. Approximately 97 percent of registered investment companies (4,850) report that they maintain assets in securities depositories. Assuming that a proportionate number of small entities use securities depositories, then approximately 233 registered investment companies that are small entities will be affected by the rule amendments.

<sup>46</sup> A bank is considered by the Small Business Administration to be a small entity if it has less than \$150 million in assets. See 13 CFR 121.201 (1999). See also 5 U.S.C. 601(3).

<sup>47</sup> This includes approximately 12 Federal Reserve Banks and 13 registered clearing agencies.

<sup>48</sup> See *supra* Section II.C.

<sup>49</sup> Rule 17f-4(a) and (b)(1).

<sup>50</sup> Rule 17f-4(a)(1).

<sup>51</sup> Rule 17f-4(b)(1)(i).

<sup>52</sup> Rule 17f-4(a)(2).

<sup>53</sup> Rule 17f-4(b)(1)(ii).

(1) Is at a minimum obligated to exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain such financial assets;

(2) Is required to provide, promptly upon request by the fund, such reports as are available concerning the internal accounting controls and financial strength of the custodian; and

(3) Requires any intermediary custodian at a minimum to exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain financial assets corresponding to the security entitlements of its entitlement holders.

(b) *Direct dealings with securities depository.* A fund may place and maintain financial assets, corresponding to the fund's security entitlements, directly with a securities depository, if:

(1) The fund's contract with the securities depository or the securities depository's written rules for its participants:

(i) Obligate the securities depository at a minimum to exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain financial assets corresponding to the fund's security entitlements; and

(ii) Requires the securities depository to provide, promptly upon request by the fund, such reports as are available concerning the internal accounting controls and financial strength of the securities depository; and

(2) The fund has implemented internal control systems reasonably designed to prevent unauthorized

officer's instructions (by providing at least for the form, content and means of giving, recording and reviewing all officer's instructions).

(c) *Definitions.* For purposes of this section the terms:

(1) *Clearing corporation, financial asset, securities intermediary, and security entitlement* have the same meanings as is attributed to those terms in § 8-102, § 8-103, and §§ 8-501 through 8-511 of the Uniform Commercial Code, 2002 Official Text and Comments, which are incorporated by reference in this section pursuant to 5 U.S.C. 552(a) and 1 CFR part 51. The Director of the Federal Register has approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the Uniform Commercial Code from the National Conference of Commissioners on Uniform State Laws, 211 East Ontario Street, Suite 1300, Chicago, IL 60611. You may inspect a copy at the following addresses: Louis Loss Library, U.S. Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549, and Office of the Federal Register, National Archives and Records Administration, 800 North Capitol Street, NW, Suite 700, Washington, DC.

(2) *Custodian* means a bank or other person authorized to hold assets for the fund under section 17(f) of the Act (15 U.S.C. 80a-17(f)) or Commission rules in this chapter, but does not include a fund itself, a foreign custodian whose use is governed by § 270.17f-5 or § 270.17f-7, or a vault, safe deposit box, or other repository for safekeeping maintained by a bank or other company whose functions and physical facilities are supervised by a federal or state

authority if the fund maintains its own assets there in accordance with § 270.17f-2.

(3) *Fund* means an investment company registered under the Act and, where the context so requires with respect to a fund that is a unit investment trust or a face-amount certificate company, includes the fund's trustee.

(4) *Intermediary custodian* means any subcustodian that is a securities intermediary and is qualified to act as a custodian.

(5) *Officer's instruction* means a request or direction to a securities depository or its operator, or to a registered transfer agent, in the name of the fund by one or more persons authorized by the fund's board of directors (or by the fund's trustee, if the fund is a unit investment trust or a face-amount certificate company) to give the request or direction.

(6) *Securities depository* means a clearing corporation that is:

(i) Registered with the Commission as a clearing agency under section 17A of the Securities Exchange Act of 1934 (15 U.S.C. 78q-1); or

(ii) A Federal Reserve Bank or other person authorized to operate the federal book entry system described in the regulations of the Department of Treasury codified at 31 CFR 357, Subpart B, or book-entry systems operated pursuant to comparable regulations of other federal agencies.

Dated: February 13, 2003.

By the Commission.

**Margaret H. McFarland,**  
*Deputy Secretary.*

[FR Doc. 03-4042 Filed 2-19-03; 8:45 am]

**BILLING CODE 8010-01-P**

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Vol. 68, No. 34

Thursday, February 20, 2003

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### FEDERAL REGISTER PAGES AND DATE, FEBRUARY

5203-5528.....	3
5529-5784.....	4
5785-6060.....	5
6061-6338.....	6
6339-6602.....	7
6603-6814.....	10
6815-7062.....	11
7063-7300.....	12
7301-7410.....	13
7411-7692.....	14
7693-7896.....	18
7897-8152.....	19
8153-8444.....	20

### CFR PARTS AFFECTED DURING FEBRUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

#### 3 CFR

##### Proclamations:

7644.....	6055
7645.....	6057
7646.....	6059
7647.....	7053

##### Executive Orders:

13285.....5203

##### Presidential Determinations:

No. 2003-13 of	
January 29, 2003.....	5785
No. 2003-14 of	
January 30, 2003.....	5787

#### 5 CFR

576.....	5529
875.....	5530
890.....	5470

##### Proposed Rules:

890.....	6649
2637.....	7844
2641.....	7844

#### 7 CFR

1.....	39
15f.....	7411
301.....	5793, 5794, 6603
318.....	5796, 5800
319.....	6544
330.....	6341
354.....	6341
762.....	7693
764.....	7693
774.....	7693
1000.....	7063
1001.....	7063
1005.....	7063
1006.....	7063
1007.....	7063
1030.....	7063
1032.....	7063, 7070
1033.....	7063
1124.....	7063
1126.....	7063
1131.....	7063
1135.....	7063
1413.....	5205
1755.....	7897
1910.....	7693
1924.....	7693
1941.....	7693
1943.....	7693
1951.....	7693
1955.....	7693
1956.....	7693
1962.....	7693
1965.....	7693

##### Proposed Rules:

319.....	6352
360.....	6653
1466.....	6655
1470.....	7720

#### 9 CFR

4.....	6341
11.....	6341
12.....	6341
49.....	6341
50.....	6341
51.....	6341
52.....	6341
53.....	6341
54.....	6341
70.....	6341
71.....	6341
72.....	6341
73.....	6341
74.....	6341
75.....	6341
77.....	6341
78.....	6341
79.....	6341
80.....	6341
82.....	7412
85.....	6341
89.....	6341
91.....	6341
92.....	6341
93.....	6341, 7414
94.....	5802, 6341
95.....	6341
96.....	6341
97.....	6341
98.....	6341
99.....	6341
122.....	6341
123.....	6341
124.....	6341
130.....	6341
145.....	6341
147.....	6341
160.....	6341
161.....	6341
162.....	6341
166.....	6341, 7415

##### Proposed Rules:

94.....6673, 7722

#### 11 CFR

110.....6346

##### Proposed Rules:

100.....	7728
110.....	7728

#### 12 CFR

211.....	7898
272.....	6061
303.....	7301
1750.....	7309
1805.....	5704
1806.....	5717

##### Proposed Rules:

3.....	6363
5.....	6363
6.....	6363



7.....6363	<b>18 CFR</b>	4041a.....7454	4.....6998
9.....6363	375.....6608	4043.....7454	<b>40 CFR</b>
28.....6363	390.....7416	4050.....7454	9.....7176
34.....6363	<b>20 CFR</b>	4062.....7454	52.....5221, 5228, 6627, 6629, 7174, 7321, 7428, 7704
609.....5595	260.....6820	4203.....7454	61.....6082
611.....5587	320.....6820	4204.....7454	62.....6630, 6633
612.....5587	404.....5210	4207.....7454	63.....6635, 7706
614.....5587, 5595	416.....5210	4211.....7454	81.....7174, 7410, 8185
615.....5595	<b>21 CFR</b>	4219.....7454	122.....7176
617.....5587, 5595	58.....6609	4220.....7454	123.....7176
<b>13 CFR</b>	73.....7416	4221.....7454	180.....5835, 5839, 5847, 7428, 7931, 7935
<b>Proposed Rules:</b>	201.....6062	4231.....7454	412.....7176
120.....5234	349.....7919	4245.....7454	<b>Proposed Rules:</b>
121.....5234	522.....8153	4281.....7454	52.....5246, 5263, 6681, 7327, 7330, 7476
<b>14 CFR</b>	529.....5562	4901.....7454	62.....6681, 6682
23.....5538	558.....6820	4902.....7454	63.....7735
25.....5208	866.....5825	4903.....7454	180.....7097
39.....5541, 5805, 5808, 5810, 5812, 5815, 5818, 5819, 5822, 6347, 6815, 7652, 7900, 7902, 7904, 7908, 7910, 7911	<b>Proposed Rules:</b>	4907.....7454	<b>41 CFR</b>
71.....6606, 6607, 7652, 7913, 7914, 7915, 7916	1.....5378, 5428	<b>30 CFR</b>	109-6.....7940
73.....7917	101.....8163	100.....6609	Ch. 302.....7941
91.....7684	349.....7951	250.....7421, 8402	<b>42 CFR</b>
95.....7918	1301.....7728	<b>Proposed Rules:</b>	405.....6636
97.....6816, 6818	<b>22 CFR</b>	206.....7085, 7086	419.....6636
119.....5782	120.....7417	917.....6838	<b>Proposed Rules:</b>
121.....5782	123.....6609	934.....6842	413.....6682
129.....5782	<b>Proposed Rules:</b>	<b>31 CFR</b>	<b>44 CFR</b>
135.....5782	307.....5857	103.....6613	64.....5852
150.....6608	<b>23 CFR</b>	321.....7427	65.....6644, 6823, 6826
183.....5782	450.....7418	351.....7427	67.....6828, 6830
<b>Proposed Rules:</b>	636.....7921	352.....7427	<b>Proposed Rules:</b>
1.....6802	<b>Proposed Rules:</b>	353.....7427	61.....5264
39.....5610, 5856, 6376, 6379, 6380, 6382, 6383, 7081, 7084, 7449, 7451, 7947, 8155, 8157, 8161	1225.....6091	359.....7427	67.....6847, 6861
71.....5613, 6677, 7949	<b>24 CFR</b>	360.....7427	<b>45 CFR</b>
91.....6802	234.....6396	501.....6820	160.....8334
121.....6802	<b>Proposed Rules:</b>	<b>32 CFR</b>	162.....8334, 8381
125.....5488, 6802	902.....6262	199.....6617	164.....8334
135.....5488, 6802	3500.....6385	254.....6082	1602.....7433
255.....7325	<b>26 CFR</b>	706.....5827, 5828, 5829, 5830, 5831	1611.....7718
<b>15 CFR</b>	1.....5346, 6081, 6350	<b>Proposed Rules:</b>	<b>46 CFR</b>
2016.....5542	157.....7922	322.....8179	356.....5564
<b>16 CFR</b>	602.....7922	<b>33 CFR</b>	<b>Proposed Rules:</b>
1512.....7072	<b>Proposed Rules:</b>	117.....5832, 6621, 7427	401.....7489
<b>17 CFR</b>	1.....7453, 7454	165.....5833, 7073, 7075, 7078, 7701, 7926	<b>47 CFR</b>
1.....5545	41.....7454	<b>Proposed Rules:</b>	32.....6351
30.....5545	48.....7454	117.....5858, 6100, 7087	52.....7323
190.....5545	145.....7454	165.....5614, 6844, 7093, 7471, 7473, 7958, 7960	53.....6351
205.....6296	157.....7956	179.....7096	54.....6646, 6832
210.....6006	602.....7956	181.....7096	64.....6351, 6352
228.....5982	<b>27 CFR</b>	183.....7096	73.....5583, 5584, 5854, 5855, 6082, 7944
229.....5982	<b>Proposed Rules:</b>	385.....5860	<b>Proposed Rules:</b>
239.....6564	55.....7410, 8331	<b>34 CFR</b>	0.....6689
240.....5348, 6006	<b>28 CFR</b>	34.....8142	43.....6689
249.....5348, 5982, 6006, 6564	105.....7313	<b>36 CFR</b>	63.....6689
270.....5348, 6564, 8438	522.....5563	242.....7276, 7298, 7703	64.....6689
274.....5348, 6006, 6564	<b>29 CFR</b>	<b>Proposed Rules:</b>	73.....5616, 5617, 5860, 5861, 5862, 7737, 7961, 7962, 7963, 7964
275.....6585	4022.....7419	242.....7294, 7734	74.....7737
<b>Proposed Rules:</b>	4044.....7419	<b>37 CFR</b>	76.....7737
201.....8138	<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	90.....6687, 6688, 7737
205.....6324	4000.....7454	201.....6678	<b>48 CFR</b>
240.....6324	4003.....7454	<b>38 CFR</b>	201.....7438
249.....6324	4007.....7454	19.....6621	202.....7438
270.....7038	4010.....7454	36.....6625	
275.....7038	4011.....7454	<b>Proposed Rules:</b>	
	4022.....7454	3.....6679, 6998	
	4041.....7454		

204.....	7438	250.....	7438	<b>49 CFR</b>	622.....	6360
206.....	7438	252.....	7441	571.....	648.....	6088
209.....	7438	253.....	7438	1540.....	679.....	5585, 6833, 7323, 7448,
212.....	7438	923.....	6355	1570.....		7719, 8153, 8154
214.....	7438	936.....	6355	1572.....	<b>Proposed Rules:</b>	
217.....	7438	970.....	6355	<b>Proposed Rules:</b>	17.....	6863
219.....	7438	1804.....	5230	173.....	20.....	6697
225.....	7441	1827.....	5230	192.....	21.....	6697
230.....	7438	1835.....	5230	571.....	92.....	6697
231.....	7438	1852.....	5230	1180.....	100.....	7294, 7734
232.....	7438	<b>Proposed Rules:</b>		<b>50 CFR</b>	300.....	6103
236.....	7438	2.....	5774	17.....	600.....	6863, 7492
237.....	7443	31.....	5774	100.....	648.....	7749, 7965
239.....	7438	52.....	5778	223.....	679.....	6386, 6865, 7750
242.....	7438	228.....	7490			
249.....	7438	252.....	7491			

**REMINDERS**

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

**RULES GOING INTO EFFECT FEBRUARY 20, 2003****HEALTH AND HUMAN SERVICES DEPARTMENT****Food and Drug Administration**

Animal drugs, feeds, and related products:

Oxytetracycline injection; published 2-20-03

**TRANSPORTATION DEPARTMENT****Federal Aviation Administration**

Air traffic operating and flight rules, etc.:

Grand Canyon National Park, AZ; special flight rules in vicinity—

Special flight rules area and flight free zones; modification of dimensions; published 12-5-01

Airworthiness directives:

Airbus; published 2-5-03

Boeing; published 2-5-03

Pratt & Whitney Canada; published 2-5-03

Class E airspace; published 11-13-02

Class E2 and Class E5 airspace; published 1-3-03

Restricted areas; published 1-23-03

**COMMENTS DUE NEXT WEEK****COMMERCE DEPARTMENT****National Oceanic and Atmospheric Administration**

Fishery conservation and management:

Alaska; fisheries of Exclusive Economic Zone—

Pacific halibut and sablefish; comments due by 2-24-03; published 1-24-03 [FR 03-00704]

Magnuson-Stevens Act provisions—

Bering Sea and Aleutian Islands king and tanner crabs; fishing capacity reduction program; comments due by 2-27-

03; published 1-28-03 [FR 03-01908]

Domestic fisheries; exempted fishing permit applications; comments due by 2-26-03; published 2-11-03 [FR 03-03291]

**ENERGY DEPARTMENT****Federal Energy Regulatory Commission**

Natural gas companies (Natural Gas Act):

Interstate natural gas facilities; emergency reconstruction; comments due by 2-27-03; published 1-28-03 [FR 03-01698]

**ENVIRONMENTAL PROTECTION AGENCY**

Air pollutants, hazardous; national emission standards:

Automobile and light-duty truck surface coating operations; comments due by 2-24-03; published 1-2-03 [FR 02-33144]

**ENVIRONMENTAL PROTECTION AGENCY**

Air programs:

Stratospheric ozone protection—  
Ozone-depleting substances; substitutes list; comments due by 2-26-03; published 1-27-03 [FR 03-01623]

**ENVIRONMENTAL PROTECTION AGENCY**

Air programs:

Stratospheric ozone protection—  
Ozone-depleting substances; substitutes list; comments due by 2-26-03; published 1-27-03 [FR 03-01624]

Air programs; approval and promulgation; State plans for designated facilities and pollutants:

Alabama; comments due by 2-27-03; published 1-28-03 [FR 03-01868]

**ENVIRONMENTAL PROTECTION AGENCY**

Air programs; approval and promulgation; State plans for designated facilities and pollutants:

Alabama; comments due by 2-27-03; published 1-28-03 [FR 03-01869]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

California; comments due by 2-24-03; published 1-23-03 [FR 03-01362]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

California; comments due by 2-24-03; published 1-23-03 [FR 03-01363]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

Florida; comments due by 2-26-03; published 1-27-03 [FR 03-01632]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

Florida; comments due by 2-26-03; published 1-27-03 [FR 03-01633]

Nevada; comments due by 2-27-03; published 1-28-03 [FR 03-01774]

South Dakota; comments due by 2-26-03; published 1-27-03 [FR 03-01775]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

Wisconsin; comments due by 2-24-03; published 1-24-03 [FR 03-01516]

**ENVIRONMENTAL PROTECTION AGENCY**

Air quality implementation plans; approval and promulgation; various States:

Wisconsin; comments due by 2-24-03; published 1-24-03 [FR 03-01517]

Solid wastes:

Waste management system; testing and monitoring activities; methods innovation; comments due by 2-28-03; published 1-16-03 [FR 03-00957]

Superfund program:

National oil and hazardous substances contingency plan—

National priorities list update; comments due by 2-28-03; published 1-29-03 [FR 03-01776]

Small Business Liability Relief and Brownsfields Revitalization Act; innocent landowners; standards and practices

for all appropriate inquiry; comments due by 2-24-03; published 1-24-03 [FR 03-01630]

**ENVIRONMENTAL PROTECTION AGENCY**

Superfund program:

Small Business Liability Relief and Brownsfields Revitalization Act; innocent landowners; standards and practices for all appropriate inquiry; comments due by 2-24-03; published 1-24-03 [FR 03-01631]

**FEDERAL COMMUNICATIONS COMMISSION**

Common carrier services:

Wireless telecommunications services—

Telephone numbers portability; wireline carriers obligation; comment request; comments due by 2-26-03; published 2-13-03 [FR 03-03136]

Radio stations; table of assignments:

Texas; comments due by 2-24-03; published 1-21-03 [FR 03-01199]

**FEDERAL DEPOSIT INSURANCE CORPORATION**

Practice and procedure:

Filing procedures, corporate powers, international banking, and management official interlocks; technical corrections and modifications; comments due by 2-25-03; published 12-27-02 [FR 02-31921]

**HOMELAND SECURITY DEPARTMENT**

Classified national security information and access regulations; comments due by 2-26-03; published 1-27-03 [FR 03-01995]

Federal or State litigation; production or disclosure of official information; comments due by 2-26-03; published 1-27-03 [FR 03-01997]

Freedom of Information Act and Privacy Act; implementation; comments due by 2-26-03; published 1-27-03 [FR 03-01996]

**INTERIOR DEPARTMENT Fish and Wildlife Service**

Endangered and threatened species:

Critical habitat designations—  
Cactus ferruginous pygmy-owl; Arizona

distinct population segment; comments due by 2-25-03; published 11-27-02 [FR 02-29617]

Preble's meadow jumping mouse; comments due by 2-27-03; published 1-28-03 [FR 03-01803]

#### **JUSTICE DEPARTMENT Drug Enforcement Administration**

Privacy Act; implementation; comments due by 2-26-03; published 1-27-03 [FR 03-01670]

#### **LABOR DEPARTMENT Labor-Management Standards Office**

Labor-management standards: Labor organization annual financial reports; comments due by 2-25-03; published 12-27-02 [FR 02-32445]

#### **NATIONAL CREDIT UNION ADMINISTRATION**

Credit unions: Investment and deposit activities and Regulatory Flexibility Program; comments due by 2-25-03; published 12-27-02 [FR 02-32496]

#### **TRANSPORTATION DEPARTMENT**

##### **Coast Guard**

Ports and waterways safety: Puget Sound, WA; protection of tank ships; security zone; comments due by 2-25-03; published 12-27-02 [FR 02-32721]

#### **TRANSPORTATION DEPARTMENT**

Computer reservation systems, carrier-owned:

Expiration date extension; comments due by 2-28-03; published 2-13-03 [FR 03-03606]

Privacy Act; implementation; comments due by 2-24-03; published 12-24-02 [FR 02-31755]

#### **TRANSPORTATION DEPARTMENT**

##### **Federal Aviation Administration**

Air carrier certification and operations:

Foreign operated transport category airplanes; flightdeck security concerns; comments due by 2-28-03; published 12-30-02 [FR 02-32946]

#### **TRANSPORTATION DEPARTMENT**

##### **Federal Aviation Administration**

Air traffic operating and flight rules, etc.:

Alaska; Instrument Flight Rules Area Navigation operations using Global Positioning Systems (SFAR No. 97); comments due by 2-24-03; published 1-24-03 [FR 03-01601]

Airworthiness directives:

Boeing; comments due by 2-24-03; published 1-8-03 [FR 03-00333]

British Aerospace; comments due by 2-28-03; published 1-27-03 [FR 03-01677]

Pilatus Aircraft Ltd.; comments due by 2-24-03; published 1-14-03 [FR 03-00672]

#### **TRANSPORTATION DEPARTMENT Federal Aviation Administration**

Class E airspace; comments due by 2-28-03; published 1-6-03 [FR 03-00061]

#### **TRANSPORTATION DEPARTMENT**

##### **Federal Aviation Administration**

Class E airspace; comments due by 2-28-03; published 1-17-03 [FR 03-01133]

#### **TRANSPORTATION DEPARTMENT**

##### **Federal Aviation Administration**

Class E airspace; comments due by 2-28-03; published 1-17-03 [FR 03-01132]

#### **TREASURY DEPARTMENT**

##### **Alcohol, Tobacco and Firearms Bureau**

Firearms:

Commerce in explosives—  
Explosive pest control devices; comments due by 2-28-03; published 1-29-03 [FR 03-01945]

#### **LIST OF PUBLIC LAWS**

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-741-6043. This list is also available online at <http://www.nara.gov/fedreg/plawcurr.html>.

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#### **H.R. 16/P.L. 108-6**

To authorize salary adjustments for Justices and judges of the United States for fiscal year 2003. (Feb. 13, 2003; 117 Stat. 10)

Last List February 11, 2003

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